CONFORMITY ASSESSMENT SCHEME by Continua

Version 1.0

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Abstract

The purpose of this document is to describe the Conformity Assessment Scheme by Continua in terms of its role in the healthcare ecosystem, how it is governed from the business perspective, what is developed and how from the technical perspective, the uniform rules by which the scheme is executed, and objective methods and criteria by which conformity to the Continua Design Guidelines can be certified by Continua or declared compliant by a vendor directly to their customer

Personal Connected Health Alliance

Executive Summary

The Personal Connected Health Alliance (PCHAlliance) works collaboratively with health, technology and life sciences, public policy, research and advocacy groups to support a new norm of personal health engagement, positive behaviour change, improved wellbeing and health outcomes. The PCHAlliance publishes and promotes the global adoption of the *Continua Design Guidelines* (CDG), an open framework implementation guide for user-friendly, secure and interoperable health data exchange in personal connected health. The *Continua Test and Certification* program ensures products conform to the CDG and its underlying standards and demonstrates interoperability between conforming products.

This Conformity Assessment Scheme (CAS) by Continua outlines the role of the PCHAlliance in the healthcare ecosystem and the governance by Continua to ensure quality and transparency. It clearly defines processes for developing and maintaining test cases, test plans, and test platforms. It defines consistent processes for operation of and access to recognized test facilities. Uniform execution of processes and procedures is the cornerstone of any conformity assessment scheme. Therefore, this document defines common assessment criteria, approved lab configurations, uniform standards-based test method selection based on product features, standardized test reports, and declaration statements.

CAS by Continua goes beyond assessing conformity to specifications and demonstrating interoperability across the ecosystem of Continua devices. It defines high value, transparent and objective methods and criteria for 3rd party certification of test results that are recognized worldwide. Certified products may sport the Continua logo and be listed on the Certified Products Showcase. For more price sensitive markets, CAS by Continua also outlines a more affordable yet disciplined process by which device vendors can self-declare compliance to the CDG directly to their customer.

Developed with representation from the various stakeholders, CAS by Continua achieves that delicate balance between a comprehensive and rigorous method for ensuring devices meet stated functional requirements, demonstrated in an affordable time and cost that allows vendors to be profitable in a highly competitive market. The CDG enable clarity essential in procurement of devices and services while CAS by Continua provides a transparent and universal mechanism to assure compliance with procurement requirements. This is especially valuable in the complex, demanding and highly fragmented healthcare IT market.

History

This document contains Version 1.0 of Conformity Assessment Scheme by Continua.

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Purpose

The purpose of this document is to describe the Conformity Assessment Scheme by Continua. It provides the reader with a clear understanding of how to demonstrate product conformity with the Continua Design Guidelines through conformance and interoperability testing using uniform processes and procedures.

The PCHAlliance understands the complex healthcare IT ecosystem of governments, industry, companies, customers, products, and their need for a universal conformity assessment scheme. CAS by Continua is governed by a separate legal entity that is responsible for developing, maintaining, and managing the scheme in a transparent manner with globally recognized quality processes. This ISO/IEC 17067 compliant conformity assessment scheme clearly defines how test cases and test plans are developed and maintained, test platforms are validated, test labs recognized, scopes defined and extended, conformity criteria accessed, and non-conformities resolved. Uniform methods and criteria for conformity assessment execution are clearly defined including scope, ISO/IEC standard processes for measuring conformance and interoperability, protection and publication of test results, listing of conforming products, and overall administration.

For customers requesting certification of conformity assessment results, this document clearly defines how to apply for certification, the uniform methodology essential to certification, what will be included in a statement of conformity, permitted use of logos and other marks, and requirements for maintaining certified status. It is only by successfully completing the Continua certification process that an organization may receive a Continua certification certificate and a listing on the Certified Product Showcase.

For vendors wishing to declare compliance to the Continua Design Guidelines directly to their customer, this document outlines requirements and widely recognized and uniform methods by which to clearly declare which capabilities have successfully passed pre-defined pass/fail criteria.

1 Application

This document describes the Conformity Assessment Scheme by Continua in terms of its role in the healthcare ecosystem, how it is governed from the business perspective, what is developed and how from the technical perspective, the uniform rules by which the scheme is executed, and objective methods and criteria by which conformity to the Continua Design Guidelines can be certified by Continua or declared Continua Compliant by a vendor directly to their customer.

2 Ecosystem

This CAS by Continua addresses the need for conformity assessment and interoperability across a diverse ecosystem of governments, industry, companies, and customers to ensure select health, medical and fitness products conform to the Continua Design Guidelines to provide their expected benefit.

2.1 Governments

Governments all around the world, at the international, national, and regional level are pursuing interoperable e-Health solutions with a primary objective of driving down the cost of healthcare.

In the United States, healthcare affordable by all continues to be a major challenge. The U.S. Department of Health and Human Services works to protect health and wellbeing of all Americans by fostering advances in medicine, public health, and social services. The Center for Medicare & Medicaid Services oversees the Meaningful Use program that awards incentives for using certified electronic health records (EHRs) to improve patient outcomes. The Office of the National Coordinator for Health Information Technology promotes health IT, including electronic health records and private and secure electronic health information exchange. The FDA Center for Devices and Radiological Health (CDRH) facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

In Europe, The European Union through the European Commission set out objectives and priorities for action. The Directorate Generals for Health and Food Safety, Communications Networks, Content and Technology, and for Growth all have initiatives that promise to impact e-Health across Europe. Much of this effort is driven by Directive 2011/24/EU to facilitate access to cross-border healthcare. The Europe 2020 strategy includes the Digital Agenda to better exploit the potential of information and communications technologies to improve e-Health. The Interoperability Solutions for European Public Administrations was established to agree on a common set of standards and specifications to be used in development of e-Health systems in Europe.

In China, the central government has overall responsibility for national health legislation, policy, and administration. It is guided by the principle that every citizen is entitled to receive basic health care services, with local governments—provinces, prefectures, cities, counties, and towns—responsible for providing them, with variations for local circumstances. Health authorities include the National Health and Family Planning Commission and the local Health and Family Planning Commissions, which have primary responsibility for organizing and delivering health care and supervising providers (mainly hospitals). Health authorities at the prefecture, county, and town levels have limited flexibility in carrying out provincial health policies.

2.2 Industry

There are a number of industry organizations working to provide standards and specifications by which to implement government and private initiatives targeting e-health interoperability across enterprises and national boundaries.

Health Level Seven International (HL7) is dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

Integrating the Healthcare Enterprise (IHE) works to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care.

The IEEE is the world's largest professional association advancing innovation and technological excellence for the benefit of humanity. ISO/IEEE 11073 Personal Health Data standards allow for the interoperability of Personal Health Devices (PHDs) such as weighing scales, blood pressure monitors, and blood glucose monitors.

The Bluetooth Special Interest Group (BT SIG) promotes the development and implementation of Bluetooth technology. Bluetooth Low Energy is a popular short-range wireless solution that can be used in the health and fitness market. The Sports and Fitness Working Group works to enable interoperability among sports & fitness devices and systems used to improve users' physical fitness. The Medical Devices Working Group develops specifications to enable more rigorous exchange of data between medical, health and fitness devices.

The Healthcare Information and Management Systems Society (HIMSS) is a global, cause-based, not-for-profit organization focused on better health through information technology. A wholly owned subsidiary of HIMSS, the Personal Connected Health Alliance (PCHAlliance) is the leading organization convening, constraining and

advocating global technology standards to advise developers of end-to-end interoperable solutions for personal connected health.

The ITU Telecommunications Standardization Sector (ITU-T) creates non-binding Recommendations via standards that define how telecommunication networks operate and interwork. Within ITU-T Study Group 16, the eHealth Standardization Coordination Group is a platform to promote stronger coordination amongst the key players in all the technical areas of e-Health standardization. ITU-T H.810 "Interoperability Design Guidelines for Personal Health Systems" is the international standard version of the PCHAlliance Continua Design Guidelines.

COCIR is the European Trade Association representing the medical imaging, health ICT and electro-medical industries. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. Its vision and mission is a better world with improved access to affordable, safe, and quality healthcare.

European Commission Decision 2011/C 349/04 established the European Multi-Stakeholder Platform on ICT Standardization tasked to advise the Commission on all matters related to European ICT standardization policy and its effective implementation, including identifying future ICT standardization and specification needs and mandates.

The Comité Européen de Normalisation (CEN) is an association that brings together the National Standardization Bodies of 33 European countries. CEN/TC 251 delivers and maintains health informatics standards for Europe, preferably by producing them in co-operation with other SDOs at a global level and by adopting standards from other SDOs.

CENELEC is the European Committee for Electro-technical Standardization and is responsible for standardization in the electro-technical engineering field. CENELEC prepares voluntary standards, which help facilitate trade between countries, create new markets, cut compliance costs and support the development of a Single European Market.

The European Telecommunications Standards Institute (ETSI) produces globally applicable standards for Information and Communication Technologies (ICT). Within the Technology Cluster Connecting Things, the EP eHealth project has initiated work on use cases for eHealth and Telemedicine and the Internet Clinic, addressing the security of systems and data, quality of services, interoperability and validation by testing and usability.

2.3 Companies

Hundreds of companies representing healthcare providers, government stakeholders, payers, pharmaceutical companies, device manufacturers, vendors/suppliers, and consulting firms drive the development of a broad range of healthcare IT devices. These entities develop, deliver, and consume hundreds of innovate products and services that deliver better care to more people at lower cost. They span medical imaging, information technologies, medical diagnostics, point-of-care diagnostics, patient monitoring systems, laboratory automation, patient self-testing, custom biotech solutions, medical sensors, and personal health gateways. Players from adjacent markets are moving into the healthcare IT domain. A number of traditional cellular services providers are moving into the healthcare market providing anything from remote connectivity to full up Electronic Health Record systems and patient portals.

2.4 Customers

CAS by Continua customers span governments, health ministers, healthcare providers, clinicians, device vendors, and consumers. Each customer has unique market drivers that must be understood and addressed in order for a scheme to be self-sustaining. Governments, health ministers, and healthcare providers define the functional and performance requirements that must be met by a product, including varying levels of conformity assessment rigor. Clinicians, device vendors, and consumers must meet these requirements while ensuring profitability in a highly competitive market. Therefore, CAS by Continua must constantly balance comprehensive conformity assessment while minimizing time and cost to execute.

2.5 Targeted Products

This CAS by Continua targets medical grade sensors, personal health gateways, and health & fitness servers.

Medical grade sensors include devices that standardize around the IEEE 11073 Personal Health Device family of standards for data format and exchange between the sensor and the gateway. These devices employ a variety of transports including USB, Bluetooth®, NFC and ZigBee.

Personal Health Gateways (PHG) include implementations that standardize around the IHE PCD-01 transaction and the HL7 V2 and V3 and FHIR standards to move data between a Personal Health Gateway and Health & Fitness Services (e.g. tele-health service) or a Health Information Service.

Health & Fitness Services (HFS) include products that standardize around the same HL7 standards and IHE specifications as the PHG.

Health Information Services (HIS) include products that standardize around the HL7 PHMR standard using IHE Cross-Enterprise Document Reliable Exchange (XDR) profile.

2.6 Expected Benefit

Products that implement the above specifications and demonstrate conformity with the CDG can expect to interoperate with any other Continua conformant product anywhere in the world. Furthermore, a growing number of governments and healthcare ministries already recommend compliance with the CDG and are working towards making compliance mandatory to qualify for national procurements.

There are also many practical benefits for implementing these standards and specifications per the CDG. Implementing IEEE 11073 family of standards on sensors provides medical grade data that is becoming increasingly important in supporting clinical decisions. Implementing IEEE 11073 on the gateway manager dramatically reduces life cycle costs by providing a generic observation service that can process any existing or future observation from any device that is compliant with IEEE 11073 data models and nomenclature. As an example, Gateways that implement the PHD and Services interfaces per the CDG can certify support of the HL7 V2.6 standard that is currently used in nearly all hospitals in the United States.

3 Governance

CAS by Continua is owned and operated by the PCHAlliance, which is a wholly owned subsidiary of HIMSS. Continua is a key initiative of the PCHAlliance and serves as its engineering arm. It employs a governance model that provides an overall structure and legal entity that owns and implements the scheme, a business model to ensure financial viability, and an organization to develop, maintain, and execute the conformity assessment scheme.

3.1 Legal Entity

The PCHAlliance is a not-for-profit limited liability company characterized by its Amended and Restated Operating Agreement, which includes an intellectual property rights policy.

The purpose of the Company is to establish an eco-system of interoperable personal connected health systems and services through rapid, broad and open industry adoption of existing and new standards and specifications for the interchange of personal health and wellness information between patients, vendors, doctors, and other organizations involved in the healthcare industry.

In furtherance of these efforts, the Company and its Participants seek to solicit the participation and comments of all interested parties on a fair, equitable and open basis. As part of these efforts, the Company interfaces with other groups or bodies developing standards and specifications related to the connected health platform.

The Company is responsible for driving improvements or changes into existing standards bodies where needed for interoperability of personal connected health devices. The Company acknowledges that global standards are needed to define interoperability requirements among personal connected health devices so that consumers can combine devices and services and create a full interoperable personal connected health system.

The Company further acknowledges that standards have the potential to enable innovation and grow the ecosystem in order to make personal connected health systems a reality. The Company also engages in the development of subject matter expertise, public policy positions, education, events and other such activities in furtherance of the global adoption of such standards and personal connected health.

3.2 Scheme Holder

Continua is the holder of the CAS by Continua. It includes an open organization of executive, technical, and process committees made up of member companies to ensure transparent and equitable operations. Roles & responsibilities of each of these committees are clearly defined along with specific deliverables that ensure a clear understanding and execution of the scheme.

3.2.1 Continua Council

The Continua Council is the group of Global Participants, Strategic Participants and invited thought leaders that provides strategic and technical guidance to the Board of Managers for those activities of the PCHAlliance specifically designated as related to activities of the Continua initiative. Its roles & responsibilities include:

- Governance of Committees and Work Groups
- Approve the formation of Committees and Work Groups
- Ratification of Committee and Work Group Policies & Procedures
- Approval of all Committee and Work Group Chairs
- Review and approval of all output, including to the Continua Design Guidelines

3.2.2 Executive Committee

The Executive Committee is responsible for day-to-day tactical management of Continua. Its roles & responsibilities include:

- Defining and evolving the Continua mission
- Coordination with other global, regional, or national schemes
- Establishing committees and work groups as required
- Setting specific measureable goals, objectives, and deliverables to help Continua realize its mission
- Issue resolution which can not otherwise be reached in other committees and work groups
- Approving the election of the chair and vice-chairs of other committees and work groups.
- Approving and managing the overall conformity assessment scheme

Executive Committee deliverables include:

- Conformity Assessment Scheme by Continua Strategy
- Quality Process Document
- Operating Principles
- Marketing Strategy
- Managing Finance & Accounting
- Web Site Development & Maintenance

3.2.3 Test and Certification Committee

The Test and Certification Committee is composed of target product and test domain experts from member organizations. It establishes the test methods and pass/fail criteria by which targeted products demonstrate conformity with the CDG. It defines and maintains processes and procedures to ensure uniform execution of test methods and expected results.

Roles & responsibilities include:

- Ensure the proper mapping of government, industry organization, standards development organizations, and user requirements to test plans and test methods,
- Ensure alignment with other international, national, and regional conformity assessment schemes and regulatory requirements,
- Publishing and maintaining this CAS by Continua and supporting documentation
- Recognized Test Lab Operations Management
- Certification Oversight (application processing, issue resolution, monitoring certification program and certification program web site and Certified Products Showcase).
- Self-Declaration Compliance Monitoring
- Identifying and/or qualifying subject matter experts
- Provide on-going technical support to members and prospective members
- Document control to ISO standards
- Technical Operations Management
- CESL Code Base Change Control
- Liaison with Global Technical Committee
- Test Tool Development and Maintenance

- Test Administration

See Appendix B for elaboration.

Test and Certification Committee deliverables include:

- This CAS by Continua Document
- Continua Certified Subject Matter Experts
- Accreditation Scope Definitions
- Quality Product Plan
- Conformity Assessment Test Plan
- Continua Conformity Assessment Specification
- Continua Interoperability Assessment Specification
- PHD Test Suite Structure & Test Purpose Specification
- Services Test Suite Structure & Test Purpose Specification
- HIS Test Suite Structure & Test Purpose Specification
- Test Case Database
- Continua Test Tool & Supporting Documentation
- Certification Application Process
- Declaration Statement Process
- Certification Mark License Agreement
- Logo Enforcement & Certification Advertising
- Waiver Application
- Test Lab Activation Checklist
- Certified Products Showcase
- Conforming Products Database

3.3 Organizational Structure

Continua is the engineering arm of the PCHAlliance and is responsible for developing and evolving the Continua Design Guidelines, developing and maintaining a conformity assessment program supporting certification or self-declaration, and working directly with standards and industry organizations to ensure their respective specifications properly support healthy longevity and other remote health monitoring initiatives.

3.3.1 Business Model

Continua must be self-sustaining. CAS by Continua must identify and grow revenue streams sufficient to cover expense of operations. There must be a clear advantage to 3rd party certification over self-declaration. This advantage must come in the form of business and market drivers while maintaining uniform conformity criteria. Examples of business and market drivers that may motivate vendors to certify over self-declare include:

- Encourage procurers to mandate certification to assure product compliance
- Compel vendors to certify as a means to faster and more broad market access
- Actively promote certified devices to procurers
- More prominent placement on PCHAlliance web site
- Match-making for vendors who have certified products (matching buyers to sellers)

The conformity assessment process must be the same for certification and self-declaration to the maximum extent practical while affording cost and time saving where possible. By way of example, the test tool used for certification and self-declaration should be the same to ensure uniformity of results and clarity around statements of conformance. It is the ISO/IEC 17025 accredited lab in which the tests are executed and ISO/IEC 17065-based process where results verified and promoted that provide key differentiation between certification and self-declaration.

It must also be recognized that some markets can’t afford full certification and should not be unduly penalized.

3.3.1.1 Revenue Streams

Revenue streams pursued by CAS by Continua include fees for certification, recognized Continua test labs, consulting, training, and marketing.

- The cost to execute conformity assessment testing is a business arrangement between the product vendor and the test lab.
- Vendors pay directly to the PCHAlliance a nominal fee to provide 3rd party certification of test results and promote the product on the PCHAlliance web site.
- Test labs pay directly to the PCHAlliance an administration fee to be recognized by the PCHAlliance to execute the Continua Test and Certification Plan for the purpose of certification.
- Non-member vendors pay consulting fees for PCHAlliance domain experts to help them develop and test Continua compliant devices.
- Training is provided on key elements of the Continua Design Guidelines and the underlying standards and specifications.

3.3.2 Operations

Key to the success of CAS by Continua is the availability of dedicated resources to help achieve the objectives of the scheme by effectively leveraging the domain expertise of its members. Key vice president and director level roles include:

3.3.2.1 Management

The Vice President of Continua has overall responsibility for Continua operations under supervision of the Executive Vice President of the PCHAlliance. This includes successful development and execution of the CAS by Continua.

3.3.2.2 Business Development

The role in the healthcare IT ecosystem of Continua, the Continua Design Guidelines, and Continua Conformity Assessment, must be continually promoted to governments, health ministries, healthcare providers, vendors, and test houses in order to build awareness and adoption. Specific to conformity assessment, Continua members and the industry at large has to be continually sold on the value of implementing the CDG, the purpose of conformity assessment, and the added value of certification. Pull for assessment testing and certification must be created in governments and healthcare providers, and compelling business cases need to be developed and promoted to engage the vendors.

3.3.2.3 Engineering

The design and commercial deployment of healthcare IT devices can be technically challenging. Interoperability is key to the success of healthcare, and remote healthcare in particular. Hundreds of companies are working to implement dozens of standards and specifications in order to provide connectivity and interoperability. Left alone, the industry becomes extremely fragmented and the cost of connectivity remains high. This complex maze of technical standards and specifications must be clearly understood in order to implement a conformity assessment scheme that ensures standard compliant devices do actually interoperate. While the Continua committees and work groups are rich in domain knowledge, these resources lack sufficient bandwidth to execute their plans. A dedicated engineering staff is essential to coordinating and leveraging these resources to move the plan forward.

3.3.2.4 Marketing Communications

The value of conformity assessment testing and certification is not intuitive. The largely held belief in the industry is that it only adds time and cost to a product with no value add. Furthermore, there are a number of industry organizations offering testing services. The fact that Continua is the only international initiative ensuring end-to-end ICT for personal connected health with open standards must be *continually* promoted over the claims of numerous industry and test organizations. This promotion starts with ensuring members understand the value add of CAS by Continua and can communicate it back to their member companies. It must reach outside the PCHAlliance to convince external stakeholders of the value in joining the alliance and adopting the Continua Design Guidelines and CAS by Continua.

3.4 Global Coordination

There are a number of conformity assessment schemes deployed or under development around the world. These schemes must be coordinated and leveraged in order to ensure interoperability between countries and regions while minimizing time and cost to demonstrate conformity. Schemes can be highly leveraged while acceptance criteria, properly managed, can be customized for any given region while still enjoying efficiencies and resulting economies of scale. By way of example, lab quality and domain expertise requirements and test methodologies can be common, but the number of tests and level of rigor can be customized based on product application or market economies.

3.5 Transparency

CAS by Continua operates in transparent manner to the maximum extent practical while protecting the proprietary nature of conformity data and commercialization process of its customers. To this end, the CAS by Continua organizational structure, the process by which the scheme is developed and executed, the criteria used to assess conformity, and the processes for self-declaration and certification are transparent. Devices undergoing assessment and their detailed test results are protected by confidentiality agreements.

3.6 Quality Control

Quality control processes are a cornerstone of any conformity assessment scheme. Policies and procedures must be consistently implemented across the globe to ensure uniform test results on a given product. CAS by Continua will administer this ISO/IEC 17067 compliant conformity assessment to the intent of ISO/IEC 17065.

3.6.1 Document Control

Uniform implementation starts with document control. CAS by Continua defines methods and responsibilities for controlling documents used to provide work directions, set policy, instructions, assign responsibilities, authorization, and to define methods for document establishment, issue, revision, approval, and distribution of controlled documents.

3.6.2 Document and Data Control

CAS by Continua employs a Quality Management System (QMS) to ensure the proper level of document control. Examples include, but are not limited to the Quality Manual, Quality Policies and Procedures, Work Instructions, Standards, Device Master Records, Technical Reference documents, Customer drawings/specifications, and Production documents.

3.6.3 Document and Record Naming Convention

CAS by Continua employs naming and numbering conventions as defined in the PCHAlliance Lifecycle Process document.

4 Conformity Assessment Development

Continua develops and maintains processes for the CAS by Continua. These processes define scheme scope and maintenance, development and maintenance of test cases, test plans, and test platforms, validation of test platforms, authorization of test facilities, certification of subject matter experts, scope extension, scheme access, and non-conformity resolution.

4.1 Scheme Scope

The CAS by Continua covers health medical and fitness products seeking to interoperate with other conforming products such as medical sensors, gateways, health & fitness services, health information systems, and electronic health record systems. To the maximum extent practical, the CAS by Continua will align with relevant industry standards and specifications and other conformity assessment schemes.

4.2 Scheme Maintenance

Continua defines an objective and transparent process to evolve CAS by Continua to remain relevant and current with advances in the healthcare industry and evolution of relevant standards and specifications. This process allow for input from the general membership but authorizing changes to the scheme will be the responsibility of Test & Certification Committee.

4.3 Test Case Development

Continua defines an objective and transparent process to identify and develop test cases to be used in the CAS by Continua. To the maximum extent practical, test cases will be selected that provide high value at minimum time and cost to execute. Consideration will be given to efficiency, implicit testing, opportunity to assert conformity to a set of test cases, and consideration to the class of medical device.

4.4 Test Plan Development

An objective and transparent process to assemble or redact selected test cases in a test plan. The process references relevant ISO specifications and extends or constrains those processes only as required to meet Continua requirements for efficiency. While the structure, scope, and methods of the test plans are defined herein, the actual content developed is outside the scope of this document. Test plans are modular to support customization by regional and national level implementation of CAS by Continua or other conformity assessment schemes.

The Test Plan family of documents include, in hierarchical order, the Conformity Assessment Test Plan, Test Specifications, Test Procedures, Test Cases, Test Tools, and Test Case Database.

4.4.1 Conformity Assessment Test Plan (CATP)

Whereas this document defines the processes associated with conformity assessment, the CATP defines the test plans & procedures used to demonstrate conformity of a product.

The top-level CATP outlines the high level testing approach and conformity assessment criteria for Conformance tests, Interoperability tests, Plugfest tests, Plug-a-thon tests, and how these are managed in the Test Plan Database. See “Conformity Assessment Test Plan” for all test details.

4.4.2 Test Specifications

Continua defines Test Specifications that are collections of Test Procedures (e.g. TSS&TP, CIP) for a particular functional area including details the background, approach, procedure and possible results for a test. Functional areas include:

- PHD Interface
- Services Interface
- HIS Interface

4.4.3 Test Procedures

Continua develops and maintains Test Procedures that define a step-by-step implementation of a Test Specification contained in an automated test tool or defined via manual steps. By way of example: Test Suite Structure & Test Purposes for a particular feature (e.g. Device Specialization: Weighing Scale) within a functional area (e.g. PHD Interface). Test procedures cover conformance testing and interoperability testing.

4.4.4 Test Case Documentation

Each test case to be executed must be documented to include sets of input values, execution conditions, and expected results to verify conformity with a specific requirement.

4.4.5 Test Case Database

A database that contains standards-based test cases and a mechanism to generate a Test Procedure for each product based on the features and functions it supports and assessment requested.

4.5 Test Plan Maintenance

Continua defines an objective and transparent process to maintain and evolve test plans. This includes document management and control, definition of major vs. minor releases, work in progress, release scheduling and implementation timelines, downgrading (removing a test case as a conformity criterion), and update process.

4.6 Test Platform Development

Continua defines objective and transparent process by which test platforms are developed, validated, maintained, and extended. At a minimum it includes 3rd party oversight and attestation and consensus by multiple members and/or test labs.

4.6.1 Test Tool

A Test Tool is an automated implementation of one or more Test Procedures. Test tools currently available include the Continua Test Tool and the Continua Enabling Software Library (CESL).

The Test Descriptions are the primary source of documentation for the Test Tool. Because of this relationship they will be written primarily by the Test Tool Vendor. TCC will review the Test Descriptions written by the Test Tool Vendor on a regular interval before the Test Descriptions are implemented. This process has multiple benefits. First it fulfils the requirement of an acceptance process. Secondly it will bring to light omissions, ambiguities or common misunderstandings in the specification in a timely manner. This will prevent implementation of Test Cases that might perpetuate misinterpretations and prevent a duplication of effort if the standards or Test Descriptions need to be changed.

4.7 Test Methods

Before Continua begins certification for any products implementing the Continua family of standards, Certification Specifications Documents are be created. Certification Specifications provide a plan to validate that a product meets all requirements of the PHD, Services and HIS interfaces. There is a Certification Specification for each Certified Capabilities Class. A product wishing to obtain certification from Continua must be able to pass all applicable test suites and meet all applicable requirements in the Certification Specification. The Certification Specification document is a top-level document that references specific test suite specifications and sets requirements for additional certification from SDO's.

In order to verify that Continua has completely tested the product against all the mandatory requirements of the standards and Continua Design Guidelines, each standard is reviewed and testable items are identified. Test Specifications are created by grouping Test Descriptions into functional groups. Example's might include USB, PM-Store, Metric Syntax. Grouping of Test Descriptions into Test Specs is done such that an entire test spec should be applicable to a Certifiable Capabilities Class. One or more Test Specs is referenced in a Certification Specification. A product profile is a document used to describe a system under test (SUT). The document is a survey of features implemented on a device. Continua Test Descriptions are created to guide Test Implementation. This format is only required of Continua Compliance tests that are part of a Test Suite implemented in a Test Tool. Interoperability procedures may be divergent from this format.

Because conformance is necessary but not sufficient for interoperability, Continua will augment conformance testing with a constantly evolving interoperability program. This will enable Continua to detect any gaps or ambiguity in the standards and specifications Continua references or the interoperability guidelines Continua has created.

4.8 Test Platform Validation

Proper validation of test platforms helps to ensure repeatability of test results across recognized test facilities. In brief, a CCE (See Section 4.11) executes test cases on test platforms to determine whether or not the test cases executed properly. The CCE then issues a test report to the Test & Certification Committee which determines the validation state (executed properly, conditional validation due to known issues, implicit validation, failed). Other validation criteria include minimum coverage requirements, validation types, use of reference artifacts, test log analysis, and change requests.

4.9 Test Platform Maintenance

CAS by Continua test platforms are maintained under contracts to 3rd parties. Contracted maintenance and technical support services include regular updates of the Continua test tool to reflect CDG updates and managing software and documentation releases.

4.10 Test Facility Authorization

Continua defines a uniform process and objective criteria by which test labs are evaluated and authorized to conduct conformity assessment testing per the Continua Test and Certification Plan. This process utilizes ILAC recognized accreditation bodies to ensure quality and competency, outlines the role of the test facility, the process by which to apply to become an recognized test facility, scope of authorization, role of the CCE, minimum test coverage, process by which to complete the authorization, the on-going renewal process, quality requirements, competency requirements, outsourcing, and proficiency testing.

Test Labs receive authorization from Continua to perform certification testing. A lab selected by Continua undergoes an activation process whereby a Continua Staff Member visits and performs a site inspection of the facility and interview with the lab management. The staff member also witnesses the labs first certification testing. The staff member issues a report on the lab based on their experience and interview. An activation checklist contains the criteria for the site inspection and interview.

In the event of the termination of a test lab (either by the test lab or Continua) the test lab is required to provide all certification testing documentation/results based on certifications performed by the test lab for Continua.

4.10.1 Business and Management Requirements

The Continua Test Lab shall have no outstanding conflicts of interest that would raise concerns about the integrity of the results from the Test Lab. If the Test Lab has any areas of involvement that might constitute a conflict of interest they should be disclosed to Continua. If evidence is provided that mitigates the risk the lab will still be able to qualify.

4.10.2 Staff Requirements

The Test Lab shall appoint a primary business contact as the “Test Lab Manager”. The Test Lab Manager will be the primary point of contact between Continua TCC and the test lab for questions on Test Lab operation, quality or management system issues. The Primary Business contact for the lab and their experience and qualifications are provided. The Test Lab shall appoint a primary technical contact as the “Test Lab Technical Director”. The Technical Director will be the interface for questions from Continua members undergoing certification regarding tests results and will work with Continua to help resolve disputes over test results. The Test Lab shall have at least one Continua Certification Expert.

4.10.3 Testing Requirements

The Test Lab shall be able to demonstrate adherence to the Continua test and certification plan and more specifically the Certification Specifications provided by Continua when running tests. The Test Lab shall generate a test report using the Continua test tool. The Test Lab shall have sufficient equipment and proficiency at using the equipment such that problems and failures can be isolated. The Test Lab shall provide test results to the member presenting a product for certification as well as support for follow-up questions related to the test results. The Test Lab shall support storage of test results, standards and test plan versions and current errata issues used at the time of testing, customer instructions, notes, operating manuals, customer complaints or requests. Continua members shall be granted the right to witness the certification testing being conducted on their product. The Test Lab shall be able to provide Continua with statistics relative to certifications. The Test Lab should have a system in place to ensure that the product is not tampered once the certification process begins. The Test Lab shall carry out the test plan as described in the Certification Specification (via the Test Tool and Interoperability Procedures) allowing multiple executions of a test case where it may fail the first time.

4.10.4 Experience and Certifications

The Test Lab shall be accredited to ISO 17025 *General requirements for the competence of testing and calibration laboratories.*

4.10.5 Reference Product Test Bed

The test lab maintains a set of reference products in order to do interoperability testing during the certification process. Continua prefers to select the set of products that will be used for this certification, with input and advice from CCEs. Reference products are chosen by Continua based on the products registration and product profile. New registrations are evaluated by the Test Administrator and the CertAdmin. If a product implements optional or conditional features that are not already represented in the reference test bed it is a good candidate to be added to the reference test bed.

The Test administrator and the CertAdmin then notify the certifying vendor that their product has been selected as a reference product. The certifying vendor is then required to provide a product to the test lab as long as it is still part of the reference product test bed.

The Test Administrator with the CertAdmin maintain an official reference product list. Products remain on the reference product list for a minimum of 6 months. This list will not exceed 10 products for a given product specialization. If additional products are added to the list that would cause the total number of products to exceed 10, then products will be removed from the list to lessen the maintenance and storage burden on the test labs. At

the point a product is removed from the reference product list it will be returned to the certifying company to be disposed of.

4.11 Continua Certified Expert

Continua Certified Experts (CCE) are an essential resource for any conformity assessment scheme. They are industry-recognized experts of the standards and specifications against which conformity is being assessed and experts on the CAS by Continua itself. CCEs help ensure proper development of the scheme, help regional and national adopters and implementers align with the scheme, and help users successfully navigate the scheme. Continua defines objective and transparent criteria for becoming recognized as a CCE.

The current list of CCEs are shown on the PCHAlliance public site: http://www.pchalliance.org/continua-certified-experts-cce

The recognition process is also shown on the PCHAlliance public site: http://www.pchalliance.org/continua-certification-experts-recognition-process

4.12 Scope Extensions

As a matter of efficiency to help CAS by Continua and its implementation entities evolve with new product implementations, Continua defines objective and transparent criteria by which labs can extend the scope of their accreditations, compliant with ISO guidelines.

4.13 Scheme Access Criteria

The CAS by Continua is available to the public. This allows anyone to understand the governance of the scheme and the CAS development, execution, certification, and self-declaration processes. This enables anyone to certify or self-declare their conformity to the CDG.

The results of the conformity assessment are the property of the vendor requesting the testing. The vendor pursuing self-declaration is required to retain test results and make them available to the customer upon request. The vendor seeking certification is required to share the test results with select members of the Test & Certification Committee (Conformity Assessment Body) in order to validate the test methods and results.

4.14 Non-Conformity Resolution

It is the responsibility of the parties involved in discovering a non-conformity to reach resolution per CAS by Continua established processes and procedures. In the event that resolution can't be reached, either the recognized test facility or the vendor may initiate the CAS by Continua Resolution Process.

Continua requires that the test lab submit test results as generated by the Test Tool, even if the failures are caused by an error of the test tool or specification. For each test case that the product under test has failed an "Application for Test Case Waiver" must be submitted to the CertAdmin in order for the vendor to receive Continua Certification or declare Continua Compliance. Where a product has received an Inconclusive result, it is the test engineer's responsibility to drive the verdict to either PASS or FAIL. Inconclusive Results may be due to the test tool not being able to determine the verdict so the test may need to be run manually in order to verify the result (an alternate approach to verify a PASS result is required). The test engineer shall work with either a CCE, a senior engineer or the test lab manager (not by him or herself alone) in this assessment. The test report shall show the history and reasoning for any decisions made by the test lab in documenting as a PASS verdict. Where an alternate approach is found, it is the CCEs responsibility to update the inconclusive spread sheet.

Waivers are only applicable for an error in the Continua Test Tool or in the Continua Design Guidelines or underlying standards/specifications. They cannot be used for a faulty product under test. Vendors or test labs may submit waiver applications. In general, test labs will provide assistance, but vendors will submit the actual waiver application. Vendors are encouraged to review carefully all waivers being submitted by the Test Lab on their behalf. The waiver application will allow the Vendor, or test lab to indicate the issue and if they believe that the test tool, standards or test procedures are in error. Waivers are a normal part of the certification process and over time help to create better tests, standards and certification programs.

An "Interoperability Issue Report Form" is used to report an interoperability issue.

5 Conformity Assessment Execution

CAS by Continua defines the uniform processes essential for consistent execution of conformity assessment. These processes include scheme scope, conformity assessment criteria, standard test procedures, approved test platforms, approved lab configurations, use of recognized test labs, uniform test execution, standard test reporting, compliance folders, test report publishing, conforming products listing, contracts, and records security.

5.1 Scheme Scope

CAS by Continua consists of the conformance and interoperability testing.

Conformance testing ensures that Continua Certified products conform to Continua Design Guidelines and specifications when connected in a personal health system. It further ensures those Continua Certified products implement all Continua Design Guidelines required for their Certified Capabilities Class.

Interoperability testing ensures that Continua products are able to interoperate with each other or with Continua reference products when connected. Interoperability testing for the purposes of certification is limited to procedures that run the product though the normal behaviours expected for the product type. The product being certified will be paired against up to three reference products which have already achieved certification. These products are selected from a list of pre-approved certified products by the testing lab or the vendor if self-declaration is available.

The following types of testing are specifically out of scope: non-functional, safety and efficacy, user interface, and white-box. For certification testing, at either a test lab or through first-party certification, whichever applies, a complete solution is tested. This ensures that the product under test can be fully tested for conformance; via the Continua test tool, and interoperability using reference products.

5.2 Conformity Assessment Criteria

Continua has a pre-determined, comprehensive set of requirements that a product shall meet in order to demonstrate conformity assessment and be awarded Certification.

The list of test cases required for a product to be certified shall be determined by the Vendor by cross-referencing the list of features supported by the product with the current Conformity Assessment Criteria as determined by the TCC. This task shall be accomplished using the Continua Test Tool.

The product features and functions required as part of the conformity assessment criteria will continue to evolve over time. As these changes occur, products will not have to be re-certified to the new requirements; except where additional features and functions are changed in a product (i.e., a change in memory or processor may have an effect on the size, format or timing of the data produced).

5.3 Standard Test Procedures

Standard test procedures are a cornerstone of a conformity assessment scheme and certification. Conformity assessment testing must be executed in a uniform manner of defined feature sets using approved test procedures on approved test platforms in an approved lab configuration. Test Reports must follow an expected format for easy consumption.

5.3.1 Defined Feature Sets

A product profile is a document used to describe a system under test (SUT). The document is a survey of features implemented on a product.

This document is created using the certification web site. The user fills in a form indicating the features of the product under test. This form will generate an xml product profile document. The product profile document contains information enough to determine every part of the specification that applies to the SUT. This product profile document is used for multiple purposes in Continua.

- Used by the automated test tool to select test suites and test cases that are applicable to the SUT.
- Used in the certified product database as a record of what the certified product implements for features.
- Used as part of the certification documentation so that third parties can determine what other products will be interoperable with this product.
- Used by Continua to create reports of which features of the Continua products are present in certified products.

5.3.2 Approved Test Procedures

This document provides for the conformance and interoperability testing of transports, 20601 features, PHD Interfaces, Services Interfaces, and HIS Interfaces.

5.3.2.1 Transport Test Procedures

A Continua conformant product may utilize one or more of the transports specified within the CDG. For a PHD and PHG, these are Bluetooth®, Bluetooth low energy, NFC, ZigBee and USB. For an HFS and HIS, a product may utilize one or more of the transports specified within the CDG. These are SOAP, RESTful HTTP, MQTT for the Services interfaces and IHE XDR, IHE XDM and DIRECT for the HIS interfaces.

Where an underlying transport requires its own certification, a Continua compliant product shall provide proof of having passed this certification before becoming Continua certified (e.g., Bluetooth SIG, USB-IF, Zigbee Alliance, GCF and PTCRB each have certification programs for the applicable transport profiles).

5.3.2.2 20601 Features Test Procedures

All Continua conformant products using the PHD interface shall implement the required ISO/IEEE specifications referenced within the CDG. The ISO/IEEE 11073-20601 protocol and the 11073-104** device specifications provide a framework of features and mechanisms that are utilized by a Vendor to create a medical-grade product whose data is understood end-to-end (e.g., within an EHR).

Where the Bluetooth low energy transport is selected by a Vendor, it shall implement the Bluetooth Transcoding Whitepaper as specified within the CDG. The Bluetooth Transcoding Whitepaper provides a consistent mapping of the ISO/IEEE protocol and device specializations ensuring that the product is sending medical-grade data end-to-end.

5.3.2.3 Product Test Procedures

A product shall implement one or more Certified Capability Classes (CCC) as specified within the CDG. If a product implements multiple CCCs then the test plan for all CCCs shall be executed. The Continua test tool shall be used to test each CCC implemented within a product.

5.3.2.4 PHD Interface Test Procedures

The PHD Interface testing consists of testing in three areas for both personal health devices and personal health gateways. Continua is responsible for testing data/protocol (i.e. 11073 PHD) and design guidelines and verifies testing of transport (e.g. Bluetooth®) by the transport SIGs.

The PHD certification is conducted by a Continua Certification Lab for Type A Class and certain Type D Classes (see Certification Specification document for further details), meanwhile self-testing is allowed for other Type D Classes.

In both cases, testing must be performed using the current official release of Continua Test Tool and vendor must provide a full solution for certification (i.e. software, hardware, drivers, etc.). Vendor may or may not use CESL hardware and software in its implementation.

In order to guarantee the Test Tool integrity, Continua does not allow the agent device vendor to install any driver, library, etc. in Test Tool machine. During the agent certification, the test lab shall use the Test Tool with the validated hardware components for that Test Tool version (for example: Keil USB Board, Stollmann BlueDev+P25/G2/HDP Bluetooth Board, Freescale MC13226 ZigBee dongle, CESL drivers).

5.3.2.5 Services Interface Test Procedures

The Services Interface testing includes the IHE PCD Technical Framework PCD-01 Volume 1 and Volume 2 (and implicitly, HL7 v2.6 Observation Result and Message Acknowledgment), uploading of Observations using the HL7 FHIR data model, and WS-I Basic Profile and WS-I Reliable Secure Profile.

The Services Test Program also needs to comprehend the IHE ITI Technical Framework Volume 2 Appendix V, especially V.3.2: Requirements for Transactions that don't use HL7 V3 Messages.

5.3.2.6 HIS Interface Test Procedures

The HIS interface testing involves one test suite that tests conformity to the PHMR specification as well as the Continua Design Guidelines. In addition, transport level tests on XDR and XDM (for v1.5 only) are also provided. Conformity is demonstrated through self-test and self-declaration.

5.3.2.7 Interoperability

CAS by Continua augments conformance testing with a constantly evolving interoperability program. This enables Continua to detect any gaps or ambiguity in the standards and specifications Continua references or the interoperability guidelines Continua has created. Testing is conducted in the test labs using a test bed consisting of three managers and three agents available for each device specialization. Test Labs conducting interoperability testing perform the procedures specified in the certification specification using the SUT and each of the three pair products. The SUT must pass all the procedures when paired with each of the devices.

In the case where an interoperability procedure fails the Test Lab will need to determine if the SUT or the paired product is at fault. If the paired product is at fault the Test Lab must report the failure to the CertAdmin team. The CertAdmin team will notify the product manufacturer and help guide them to take appropriate corrective action.

If at the time of the certification there are not three certified Continua products for a device specialization, the Test Lab will run interoperability pair testing against all available certified products (if any).

Note that the interoperability program against certified Continua products will not go into effect until:

1) Approved Interoperability Procedures exist for the SUT, and
2) The Test Lab or the plugfest program, has certified Continua products that can pair with the SUT.

5.3.2.7.1 PHD Interface

PHD Interface functional tests cover general procedures (e.g. single device connection), temporary measurements, PM Store, and Scanner.

5.3.2.7.2 Services Interface

The Services Interface tests cover general procedures, batch measurements, continuous measurements, and multiple connections.

5.3.2.8 Test Events

To further demonstrate interoperability, Continua hosts and participates in several Test Events such as Plugfests, Plug-a-thons, Bluetooth UnPlugFests, and others.

5.3.2.8.1 Plugfests

Because interoperability issues can't be identified a priori, Continua created a set of interoperability procedures designed to be run at Plugfests that go beyond demonstrating basic functionality and exercise error paths, simulate error conditions or try to cause products to exhibit non-conforming behaviour (known as negative testing). This suite is base-lined and version-controlled so that it can be augmented over time as new interoperability issues are discovered.

5.3.2.8.2 Plug-a-thons

Continua participates in IHE and HL7 Connect-a-thons. These connect-a-thons are a cross-vendor, live, supervised and structured testing events where industry tests implementations of standards and profiles to advance health IT interoperability. They take place annually in various countries around the world to advance health IT and patient safety.

5.3.3 Approved Test Platforms

Tests are executed using the Continua Test Tool. This tool is designed to help members pre-test their products and services and to assess conformity to the Continua Design Guidelines during formal conformity assessment testing, certification, and self-declaration. The user interface provides for editing PICS/PIXIT and general parameters, lists applicable test cases, displays logs of text case executions, and creation of certification and self-declaration documentation.

5.3.4 Approved Lab Configuration

The Test Lab shall have sufficient equipment and proficiency at using the equipment such that problems and failures can be isolated. Examples are protocol analysers and debuggers for Bluetooth, USB, 11073-X, TCP/IP and PHM. Analysis tools are not provided by Continua. The cost and acquisition of these tools is the responsibility of the test lab.

5.4 Recognized Test Labs

A test lab is place where tests are conducted under controlled scientific conditions. Where self-declaration is allowed, a vendor may perform testing of their product using the Continua Test Tool. Where 3rd party certification is required, Continua recognizes test labs who have achieved accreditation to ISO 17025 and who have passed an on-site audit by an authorized testing expert.

Continua authorizes test labs to execute testing for the express purpose of conformity assessment and certification of test results. These labs may also be used to support development testing and execution of conformity assessment testing for purposes of self-declaration.

A test lab shall keep records for a minimum of (3) years following the expiration or termination of their Continua Recognized Lab status.

5.5 Uniform Test Execution

The Test Lab shall carry out the test plan as described in the Certification Specification (via the Test Tool and Interoperability Procedures) allowing multiple executions of a test case where it may fail the first time.

Continua requires that once a product goes for certification testing a hands-off approach is adopted whereby the vendor cannot make any changes to the product and/or system under test. The Test Lab should have a system in place to ensure that the product is not tampered once the certification process begins.

5.6 Standard Test Report

Recognized test labs are required to generate test reports using the Continua Test Tool. All test results and logs referenced within the report that are to be used as evidence shall clearly map to Continua requirements. The Test Report shall provide a summary of the testing results such that the test administrator can easily determine pass/fail status.

5.7 Compliance Folder

Evidence of conformity to the Continua Test Plan shall be recorded, compiled, and maintained in a Compliance Folder by the vendor. This folder shall be maintained for a period of 3 years or as long as the product is in service, whichever is greater.

A Compliance Folder contains all the information necessary to determine which features and functions, as selected in the Product Definition Table (PDT), were tested during the Conformity Assessment of the Product and precise listings of the test cases executed and passed. Therefore, it is important to indicate exactly which features and functions were tested on a particular Product by including the PDT used to create the test plan and which version of the Conformity Assessment Test Plan was used.

5.8 Test Report Publishing

Detailed test reports are confidential to the vendor and the test lab. When pursuing Continua certification, detailed test reports are made available on a confidential basis to Continua's Certification Administration Team for validation of results. A summary test report is made available to PCHAlliance members. A final pass/fail result is available to the public via the PCHAlliance Certified Products Showcase.

5.9 Conforming Products Listing

The PCHAlliance maintains a web site featuring a Certified Product Showcase that lists Continua certified products http://www.pchalliance.org/certified-product-showcase.

5.10 Contracts

Continua maintains contracts with Recognized Test Labs to ensure compliance to this CAS by Continua. Vendors seeking to certify their products also enter into contracts with Continua governing logo usage.

5.11 Records Security

The Test Lab shall have a security system sufficient to guarantee that Continua member records will be secure and that this system is appropriately backed-up to an offsite emergency backup recovery facility (secondary storage) - The system should guarantee that only authorized personnel have access to records for Continua member companies. Additionally policies should be in place to guarantee limited access to products and intermediate results from testing sessions for member company products.

6 Certification

CAS by Continua goes beyond conformity assessment testing to issue 3rd party certification of test results. It must be clear that the certification is to the standards-based features tested and not to the overall functionality or performance of the product. Process summarized below – see Appendix A for details.

6.1 Objective

The objective of Certification is to provide governments, health ministers, healthcare providers, or any other requesting entity an impartial 3rd party confirmation that the product under procurement, or under consideration or procurement, has successfully satisfied all conformity assessment criteria per this document.

6.2 Pre-Requisites

Before a product may be certified the vendor must meet the following requirements:

1. Be a PCHAlliance Member in good standing
2. Review Certification Specification for the Applicable Certifiable Capabilities Class
3. Obtain pre-requisite certifications (Transport certifications, if applicable)

Additionally, to improve the likely hood of successful certification testing Continua strongly recommends that a product vendor:

1. Pre-Test with the Manual Test Procedures or the Continua Test Tool
2. Pre-Test Interoperability Procedures
3. Attend certification testing at the Continua Recognized Test Lab

6.3 Certification Body Requirements

Continua provides for 3rd party certification in CAS by Continua. Continua operates in a competent, consistent, and impartial manner to the intent of ISO/IEC 17065.

6.4 Certification Application Process

Application for certification is submitted directly to the PCHAlliance via the Continua Test Tool.

6.4.1 Application for Certification

Continua's goal is to provide a certification process that provides the testing of all Continua products as defined in this document, while making sure certification is as simple as possible for vendors. Continua recognizes four types of applications for certification – types A, O, D, and U. Each type of certification has a slightly different procedure and is subject to a different certification fee.

The decision as to whether a product related to an already certified product undergoes Type A, D, or U certification is determined by examining the scope of the change. The Certification Specification has the final authority in determining which types of changes warrant Type A and Type D certification.

All Continua certifications are based off of a Type A certification. The other types of certificates will point back to the original Type A certification for the purpose of auditing and change tracking.

The cost of certification is based on two fees. The listing fee is paid to the license administrator who represents Continua. The testing fee is paid directly to the test house that conducts the testing. The listing fee covers the cost of processing the application which entails verifying the registration information is correct, checking with other SDOs about existing certifications and resolving any waivers or testing issues with the product. The testing fee is negotiated with the testing lab.

6.4.2 Application Processing

New applications are processed by the Certification Administration Team (a.k.a., CertAdmin - this includes only PCHAlliance staff). CertAdmin verifies the information in the test application is complete and correct, before clearing the application's status.

If the application is for a Derivative Certification (Type D), CertAdminmust additionally verify referenced certifications, changes are properly documented, derivative certification policies understood, and verify re-test results.

If the application is for an OEM Certification (Type O), CertAdmin must verify referenced certifications and application properly completed.

If the application is for a Certificate Update (Type U), CertAdmin must verify certification application has been properly updated, how listing is to be updated, and certification updates policies are understood.

6.4.3 Recognition of a Continua Test Lab

Commercial test labs with ISO 17025 accredited scope may be recognized as a Continua test lab after completing the test lab recognition process.

A Continua recognized test lab is responsible for completing all the required tests and potential re-tests for a product as required within the Continua Test Tool (CTT). This includes all certification types (A, O, D and U) as specified within the Certification Specification. Vendors are encouraged to pre-test their product using the CTT ahead of the test lab testing. This will help ensure successful and efficient testing at the test lab.

The vendor will complete the certification application within the CTT then send to CertAdmin and to the recognized Continua Test Lab of their choice. If they would like assistance they may contact a CCE or a recognized Test Lab to help with completing the certification application. CertAdmin will review the application for accuracy and completeness and respond with its approval status within 2 business days.

Vendors are responsible for providing a product for testing which is as close to a final production product as possible. Additionally the vendor shall provide all documentation required to operate the product. It is the responsibility of both the vendor and the test lab to take care of all the logistics of shipping the product sample(s), setting reservations for testing in the Continua Test Lab and in negotiating the payment for testing.

The test lab will perform the testing on the product. This will implicitly test the technical accuracy of the certification application.

6.5 Certification Test Execution

The Test Lab will conduct the testing required by the Certification Specification and report the results back to the member company vendor. A hands-off policy is adopted within the test lab. Once the certification testing officially begins, vendors cannot modify their product’s firmware or hardware. The Test Lab will conduct testing using the version of the Test Tool and interoperability procedures indicated by the vendor in the Certification Application assuming that version abides by the following guidelines. Continua recommends that this version be the latest version of the Certification Test Tool and interoperability procedures available. However, at the discretion of the vendor a previous version of the Test Tool or interoperability procedures may be used for a period of 90 days after an updated version of the Certification Test Tool or interoperability procedures has been released.

6.5.1 Transport Certification Process

USB-IF prefers that USB certification is obtained via a Compliance Workshop, but can also be obtained by a USB approved test lab. Note that USB PHDC host transport certification will be obtained by Continua.

Bluetooth® certification can be obtained by self-declaration, that is, a product or CE manufacturer running tests independently, or at a Bluetooth® qualified test house (recommended).

The Bluetooth® Medical Device Profile test suite will be created and included in the Profile Tuning Suite (PTS), and the USB Personal Healthcare Device Class test suite will be created and included in the USB Compliance test suite.

6.5.2 HIS Self-Declaration Reviews

Reviews of the HIS Sender self-declarations consists of verifying PHM reports based on a Member running the required HIS test cases using the Test Tool against a set of PHM reports that covers all device specialization measurements and optional elements supported by the HIS direct or indirect sender. As there could be many configurations present the review duration is dependent on the number of configurations provided within a certification (number of PHM reports provided).

As the Continua Test Tool verifies both the syntax and semantics (via the XSD Parser, Schematron Templates and XPath queries) the CertAdmin's responsibility in the review is to verify that all logs are present and, within the logs, that what they claim as present in-fact present. The CertAdmin achieves this by the following steps:

1. The CertAdmin runs TamperChecker tool to verify logs have not been modified/tampered. If tampered CertAdmin records this as a discrepancy within the certification review report.
2. The CertAdmin verifies the combination of all logs supplied for a Certification includes the declared PHM report optional elements. This is achieved by verifying that all logs are present and the declared selections exist within the PHM reports received as part of the certification. If they don't the CertAdmin records this as a discrepancy within the certification review report.
3. The CertAdmin reviews the logs for the PHM Reports and verifies that the PICS string is present (this is the semantic review). If the PICS string is not present then the CertAdmin records this as a discrepancy within the certification review report.
4. The CertAdmin verifies that vendor sends specializations declared via the MDC code. If the correct MDC code is not present then CertAdmin records this as a discrepancy within his review report.

Once the review is complete the CertAdmin informs the member. Note that reviews of self-declaration may take more time than a PHD certification as the review is a manual review.

6.6 Test Report Distribution

When the Test Lab completes testing it will send all the test logs back to the Continua member vendor. Companies are encouraged to store their test logs for future reference. If a product fails testing it may opt to make fixes to the product and arrange for retesting with the test lab. This is out of scope of Continua and test results should only be turned in to CertAdmin when the vendor is satisfied with the test results produced by the test lab. It is the vendor's responsibility to formally request the Test Lab to submit the official test results to CertAdmin. Upon prompting by the Test Lab, the vendor will request that the Test Lab formally submit their results in order to achieve Continua Certification. Member company vendors are free to pre-submit information to CertAdmin if they would like additional assistance on waivers or have other questions.

The Test Lab results consist of a Test Report, which contains a summary listing the test cases that were executed and comments from the Test Lab. The Test Lab will comment on all INCONCLUSIVE and FAIL results in order to provide information to CertAdmin to enable seamless processing of waiver applications. The Test Lab also maintains the XML or HTML format Test Logs in storage; however, these are not provided to the Continua member or CertAdmin unless specifically requested.

6.7 Waiver Process

A product's certification will enter a hold status until all the applications for waivers have been processed. CertAdmin will be responsible for reviewing all applications and in making a determination to dispatch the application. See Appendix A Step 5 for details.

6.8 Statement of Conformity

The CAS by Continua certification includes a statement of conformity explicitly stating the specific capabilities that have successfully passed all certification criteria and which representations can be claimed.

A Test Report is the result of a Continua Recognized Test Lab performing the test suites outlined in the Conformity Assessment Test Plan. Each specification includes a 'Test Report Requirements' section describing the minimum requirements for a test report. This section specifies the equipment details for a certifiable product of this type, as well as the features table.

6.9 Fee Payment

CertAdmin will provide the member with a Certification Mark License Agreement and an invoice for the Continua listing fee. This is done after all certification testing issues have been resolved.

6.10 Granting Product Certification

The list below provides a summary of the items CertAdmin will verify prior to declaring a product is Continua Certified:

- The vendor is a member company and is in good standing with PCHAlliance.
- Official test lab results (signed, from Test Lab) have been received.
- Approved Waivers from CertAdmin, if any, have been received.
- Transport Certification obtained and referenced within the Certification Application.
- Completed Certification Application has been received, and CertAdminhas verified it is complete.
- Signed Certification Mark License Agreement has been received.
- Listing Fee (if applicable) has been paid to PCHAlliance.

Prior to publishing vendor information in the Certified Product Showcase, CertAdmin will verify that the information and given name of the product are accurate. Specifically, CertAdmin will check that the product name:

- Does not list support for a device specialization or functionality that isn't Continua Certified (ex. Body Composition Monitor for a Weighing Scale, or Weighing Scale for a Thermometer, or Bluetooth if only certified for USB).
- Does not imply support for more than what is Continua Certified (ex. Continua PHG for a product that does only Weighing Scale Manager functionality).
- Does not imply support for less than was certified (ex. Bluetooth stack instead of Continua Bluetooth PHG).
- Lists the transport(s) utilized.
- Lists all the device specializations supported.

6.11 Publicity

Certification requires passing all applicable tests. Once the certification process has been achieved, members receive a product certificate from CertAdmin and may then begin using the *Continua Certified logo* on their product, their packaging or any product literature (including Web pages). All certified products also receive a listing on the *Certified Product Showcase*.

6.12 Marks

The process and responsibilities for granting and enforcing logo usage are defined.

The Continua® Certification Logos are intended to represent to consumers that the associated product meets Continua certification testing requirements which support interoperability in personal health devices to offer consumers a broad set of complementary products and services. The Logo Enforcement Guide discusses the process Continua will use to ensure compliance of its Certified Logo ("logo").

A Certification Mark License Agreement is executed between the PCHAlliance and licensee whose product has been tested and found to conform with the specifications outlined in the Certification Specification Document.

PCHAlliance actively monitors and enforces logo usage.

6.12.1 Granting Logo Usage

All of the below qualifications must be met in order for the Continua Certified Logo to be provided:

- ☐ Product submitted for testing
- ☐ Test results support granting Continua certification
- ☐ Transport certification granted (where required by transport organization)
- ☐ Member is in good standing
- ☐ Certified Logo Agreement signed and received <*REFERENCE Certified Logo Agreement*>
- ☐ Listing fee is paid

Once all items are met, the Member company will receive:

1. Certified Logo Package (see Section 8 References)
2. Certified Logo and Style Guidelines (see Section 8 References)

6.12.2 Continua Certified Logo Enforcement

The legal use of the Continua Certified Logo is governed by the Certified Logo Agreement and the visual use is governed by the Certified Logo and Style Guidelines. Member companies shall closely abide by these documents.

Violators of the Certified Logo Agreement and those implementing improper use of the Continua Certified Logo will be monitored and policed by CertAdmin through industry surveillance.

6.12.3 TCC Responsibilities

The TCC's responsibilities for certification surveillance and logo enforcement are:

- Ensuring that CertAdminmonitors the Continua Certified Logo licensing and issuance process
- Ensuring CertAdminenforces proper use of the Continua Certified Logo

6.13 Certification Maintenance

The Certification Grant is valid for the lifetime of the product and subject to the configuration remaining unmodified.

7 Declaration of Compliance

7.1 Objective

To provide a freely available uniform pre-approval process enabling any vendor the ability to declare that its products are compliant to the Continua Design Guidelines through self-declaration of compliance. The availability of a public listing of Continua Compliant products will enable discovery of such products while increasing their availability and awareness in the marketplace.

To ensure that products are compliant, the process should be rigorous enough to be of value to customers (such as ministries of health, health information networks, consumers and many other stakeholders) but simple and affordable enough to encourage vendors to use as a method to promote their product to the industry. The public listing will help potential customers see products that can work within the Continua ecosystem. Installing a self-declaration process also lowers the barrier for customers who may be unable to require 3rd party certification so, for this reason alone, self-declaration may be sufficient.

7.2 Representation

It is important to note that Declaration of Compliance is governed by the business arrangements between the product vendor and the client requesting the testing in order to self-declare compliance. The PCHAlliance provides its CTT freely to any vendor with which to execute conformity assessment testing and generate a uniform declaration format. Products that successfully complete this declaration of compliance process will be listed on a PCHAlliance public web site. The PCHAlliance makes no other representations.

7.3 Accreditation Requirements

It is recommended, but not required, that laboratories conducting conformity assessment testing for the express purpose of Declaration of Compliance to the CDG be accredited to ISO 17025 "General requirements for the competence of testing and calibration laboratories." Test laboratories self-representing that they follow a quality management process and have the requisite domain expertise is preferred.

7.3.1 Quality Process

The minimum recommended quality process should follow the intent of ISO 17025. It should enable the laboratory to execute testing to the requirements of the Continua Test Plan in such a way as to meet the needs of the client and the PCHAlliance. Key personnel that have an involvement or influence on the testing activities should be identified to avoid any potential conflicts of interest.

It is recommended that the laboratory maintain a quality system appropriate to the scope of its activities. It should follow clearly documented policies and procedures, and such documentation should be under a document control system. The laboratory should have a policy and procedures for resolving complaints received from the client.

7.3.2 Competency

Laboratory management should ensure the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. This competence should be appropriate for the scope of testing.

7.4 Declarations

Entities self-declaring their compliance to the CDG must meet the following criteria using the CTT to generate Approved Test Reports.

7.4.1 Criteria

All conformity assessment criteria appropriate for the features supported by the product under test are the same regardless of pursuing certification or self-declaring compliance. This is assured through the PICS/PIXIT procedure integral to the CTT.

7.4.2 Test Platform

The product vendor shall use the latest version of the CTT.

7.4.3 Test Reports

Test results shall be created using the Test Report generator within the CTT. The CTT includes all test cases for all Continua test suites. Once the PICS, PIXITS and General Parameters are selected for a product and the Static Conformance Report (SCR) check is free of any errors, the test plan is generated showing all applicable test cases. These are the test cases that shall be performed to establish compliance.

7.4.4 Records Retention

Vendors self-declaring their compliance to the CDG shall retain records of test results for the life of the product. Summary level test results will be made available to vendor customers upon their request.

7.4.5 Statement of Compliance

The Statement of Compliance is evidence of Continua conformity provided by the vendor as part of performing self-declaration on a product. The CTT will provide this evidence after successfully executing all applicable test cases within the product's test plan. As with a Continua Certified product, a Continua Compliant product shall pass all of its applicable test cases. The only exception to this is where a waiver may be allowed. See Appendix A Step 5 for waiver process.

The CTT provides a declaration statement that defines exactly which features were found to be Continua Compliant. This Statement of Compliance clearly indicates that such compliance is the result of self-declaration and not the result of 3rd party certification.

7.5 Publicity

Vendor's self-declaring compliance to the CDG must make this declaration public information. This must specifically include notifying the PCHAlliance who may, at its sole discretion, post this information on the PCHAlliance web site. The PCHAlliance will clearly indicate self-declaration vs. 3rd party certification. Details of the testing, other than what is required on the Statement of Compliance, may be kept confidential and shared only with clients per the Records Retention policy.

7.6 Marks

Vendor's self-declaring compliance of a product or service to the CDG shall not display the Continua Certification logo in reference to the product or service.

7.7 Self-Declaration Maintenance

Self-declaration, once achieved, may be maintained for the life of the product or service for the hardware and software configuration so declared.

8 References

The following informative references exist for this document:

[1] Continua Design Guidelines http://www.pchalliance.org/continua-design-guidelines

[2] Certification Mark License Agreement https://members.pchalliance.org/wg/members/document/231
[3] Certified Logo Manual https://members.pchalliance.org/wg/members/document/231
[4] Certified Logo Usage Guidelines https://members.pchalliance.org/wg/members/document/233
[5] Continua TCC Documentation web site. Available at: https://members.pchalliance.org/wg/TCC/document
[6] ISO/IEC 9646-1 *Information technology -- Open Systems Interconnection -- Conformance testing methodology and framework -- Part 1: General concepts https://www.iso.org/standard/17473.html*
[7] Health Level Seven International (HL7) http://www.hl7.org/index.cfm
[8] Integrating the Healthcare Enterprise (IHE) http://ihe.net/
[9] IEEE http://www.ieee.org/index.html
[10] Bluetooth Special Interest Group (BT SIG) https://www.bluetooth.com/
[11] Healthcare Information and Management Systems Society (HIMSS) http://www.himss.org/
[12] ITU Telecommunications Standardization Sector (ITU-T) http://www.itu.int/en/ITU-T/Pages/default.aspx
[13] COCIR http://www.cocir.org/
[14] European Commission Decision 2011/C 349/04 https://ec.europa.eu/digital-single-market/en/news/commission-decision-28-november-2011-setting-european-multi-stakeholder-platform-ict
[15] Comité Européen de Normalisation (CEN) https://www.cen.eu/Pages/default.aspx
[16] CENELEC https://www.cenelec.eu/
[17] European Telecommunications Standards Institute (ETSI) http://www.etsi.org/
[18] The **Certified Logo Agreement** is the licensing agreement for Member company use of the Continua Certified Logo. This document must be signed in order to receive the Certified Logo Package.
[19] The **Certified Logo Package** includes the logo graphics for the Certified Logo.
[20] The **Certified Logo and Style Guidelines** include the information on appropriate use of the Certified Logo.
[21]

9 Abbreviations

BT SIG	Bluetooth Special Interest Group
CAB	Conformity Assessment Body
CAS	Conformity Assessment Scheme
CATP	Conformity Assessment Test Plan
CCC	Certified Capability Class
CCE	Continua Certification Expert
CDG	Continua Design Guidelines
CDG	Continua Design Guidelines
CDRH	Center for Devices and Radiological Health
CEN	European Committee for Standardization
CENELEC	European Committee for Electro-technical Standardization
CESL	Continua Enabling Software Library
CMLA	Certification Mark License Agreement
COCIR	European Coordination Committee of the Radiological, Electro-medical and Healthcare IT Industry
CODE	Continua Open Development Environment
CPS	Certified Product Showcase
DG	Design Guidelines
DICOM	Digital Imaging and Communications in Medicine
EHR	Electronic Health Record
ETSI	European Telecommunications Standards Institute

EU	European Union
GCF	Global Certification Forum
HFS	Health & Fitness Service
HIMSS	Healthcare Information and Management Systems Society
HIS	Health Information System
HL7	Health Level 7 International
HTML	Hypertext Markup Language
ICT	Information and Communication Technologies
IEC	*International Electro-technical Commission*
IEEE	*Institute of Electrical and Electronics Engineers*
IHE	Integrating the Healthcare Enterprise
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organization for Standardization
IT	Information Technology
ITI	IT Infrastructure
ITU-T	International Telecommunications Union Standardization Sector
LAN	Local Area Network
NFC	Near Field Communication
PAN	Personal Area Network
PCD	Patient Care Device
PCHAlliance	Personal Connected Health Alliance
PDT	Product Definition Table
PHD	Personal Health Device
PHG	Personal Health Gateway
PHM	Personal Healthcare Monitoring
PHMR	Personal Health Monitor Report
PICS	Protocol Implementation Conformance Statement
PIXIT	Protocol Implementation eXtra Information for Testing
PTCRB	Pseudo-acronym (formerly PCS Type Certification Review Board)
QMS	Quality Management System
SDO	Standards Development Organization
TCC	Test and Certification Committee
TCP/IP	Transmission Control Protocol/Internet Protocol
TF	Technical Framework
TSS&TP	Test Suite Structure & Test Purpose
US	United States of America
USB	Universal Serial Bus
WAN	Wide Area Network
WS-I	Web Services – Interoperable
XDM	Cross-Enterprise Document Media Exchange

XDR	Cross-Enterprise Document Reliable Exchange
XML	Extensible Mark-up Language

10 Glossary

Accreditation	Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
Applicable Features	Functions implemented on the SUT that are to be assessed for conformance.
Approved Test Report	Uniform test report automatically generated by the Continua Test Tool to be used as a Statement of Compliance and retained for client review.
Attestation	Issue of a statement, based on a decision following review, that fulfilment of specified requirements has been demonstrated.
Recognized Test Laboratory	A testing laboratory that has been accredited and approved by Continua to perform conformance assessment testing.
Certified	The state of being in accordance with the Continua Design Guidelines and specifications as established through 3rd party attestation per the Continua Certification Program.
Certification	The process by which the TCC certification body verifies, through conformity testing, that a personal health device complies with Continua Design Guidelines and specifications and is able to interoperate with other personal health devices compliant with the Continua Design Guidelines. A certificate of compliance and a logo will provide proof of certification.
Certification	Third-party attestation related to products, processes, systems or persons.
Certification Database	The certification database stores information on products that are currently certified by Continua and also about products that are in the process of being certified.
Certification Scheme	Stipulation of rules, procedures and management for implementing product, process and service certification.
Certification Specification	Each Certified Capabilities Class is listed in the Certification specification. This document points to the Test Procedures and Interoperability procedures that apply to the Certified Capabilities Class. This document also specifies any additional requirements for certification. An example of an additional requirement might be certification from another industry organization (for example, Bluetooth Health Device Profile certification). A device must meet the requirements of the Certification Specification and be able to pass all mandatory tests and procedures in order to achieve certification.
Certification Web Site	http://www.pchalliance.org/continua-product-certification
Certified Capabilities Class	An entity in the Continua Architecture for which a complete set of guidelines has been defined such that device can be certified to comply with such a Certified Capabilities Class.
Certified Products Showcase	The certified products showcase, uses the Certification database as a backend to display to users through a web interface products that are currently certified.

Clinical Grade Data	Patient vitals that provide clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.
Compatible	The state of demonstrated interoperability with products that have been declared Continua Compliant or Continua Certified.
Compliance	The state of being in accordance with the Continua Design Guidelines and specifications as established through 1st party declarations that the product has successfully completed testing using the Continua Test Tool.
Component	A Component is a logical entity in the Continua ecosystem. In general, for any Interface, there is a Service Component, with a well-defined set of functions depending on its type, on one side of the interface and one (or more) Client Components on the other side. Each Component is realized within a physical Device.
Conformance	An affirmative indication, through testing, that a personal health device was built and functionally behaves according to TCC interoperability specifications and Continua Design Guidelines.
Conforming Products Database	A structured set of data containing products that have successfully completed conformity assessment testing that includes product name, model number, hardware version, software version, firmware version, assessment completion date, ….
Conformity assessment	Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled
Conformity Assessment Test Plan (CATP)	Top-level test document outlines the high level testing approach and conformity assessment criteria for Conformance tests, Interoperability tests, Plugfest tests, Plug-a-thon tests, and how these are managed in the Test Plan Database.
Continua Reference System	A Continua Reference System is an OEM's reference design that can be further integrated into products by other Continua members.
Continua Services Interface (Services IF)	The Continua Services is an interface between Personal Health Gateway (e.g. smart phone, tablet and dedicate hub) and Health & Fitness Service (e.g. disease management service, ageing independently service and wellness service). The Health & Fitness Service could be hosted in the cloud. IP based connectivity is assumed between Personal Health Gateway and Health & Fitness Service and Continua focuses on defining the behaviour of the OSI Layers above IP.
Declaration	First-party attestation
Device	A Device is a physical entity (box) and contains one or more functional components and capabilities.
eHealth	Tools and services using **information and communication technologies** that can improve prevention, diagnosis, treatment, monitoring and management.
Interoperability	The ability of a client component in a device to communicate and share data with a variety of server components in an unambiguous and predictable manner to exchange data accurately, effectively and consistently. The GTC created and selected design guidelines and specifications used to certify devices will specify the technical scope and requirements by which a device is considered compliant with interoperability.
Interoperability Procedure	A manual procedure carried out between two or more member provided Continua compliant devices. Interoperability procedures are used during Plugfests and are useful for identifying common issues and specification ambiguities resulting in interoperability problems. Certification

	Specifications will also include or reference Interoperability Procedures as a requirement for certification. Interoperability procedures used for certification are generally designed to test basic operation of the device in normative operating conditions.
ISO/IEC 9646-1	*Information technology -- Open Systems Interconnection -- Conformance testing methodology and framework -- Part 1: General concepts* specifies a general methodology for testing the conformance of products to OSI specifications.
ISO/IEC 11073	*ISO/IEEE 11073 Personal Health Data* standards are a group of standards addressing the interoperability of personal health devices such as weighing scales, blood pressure monitors, and blood glucose monitors.
ISO/IEC 17000	*Conformity assessment – Vocabulary and general principles* specifies general terms and definitions relating to conformity assessment, including the accreditation of conformity assessment bodies, and to the use of conformity assessment to facilitate trade.
ISO/IEC 17011	*Conformity assessment -- General requirements for accreditation bodies accrediting conformity assessment bodies*. This International Standard specifies general requirements for accreditation bodies assessing and accrediting conformity assessment bodies (CABs).
ISO/IEC 17025	ISO standard that specifies the general requirements for the competence to carry out tests. It covers testing and calibration performed using test methods.
ISO/IEC 17065	*Conformity assessment -- Requirements for bodies certifying products, processes and services*. This International Standard contains requirements for the competence, consistent operation and impartiality of product, process and service certification bodies.
ISO/IEC 17067	*Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes*. This International Standard describes the fundamentals of product certification and provides guidelines for understanding, developing, operating or maintaining certification schemes for products, processes and services.
Original Equipment Manufacturer (OEM)	An OEM manufactures a personal healthcare device for a Product Vendor.
Personal Health Device Interface (PHD-IF)	A Personal Health Device is a Device that houses a PHD Interface Service Component that exposes PHD Interface. Examples of a Personal Health Device is glucose meter or blood pressure monitor.
Personal Health Gateway (PHG)	One of the Continua Reference Capability classes. A Personal Health Gateway is a central point of control in the Continua architecture. The Personal Health Gateway contains a number of Client Components that use Personal Health Devices and Services Interfaces to access one or more Services on other Devices to coordinate data collection, data analysis, data sharing, and alerting.
Product	An article or substance that is manufactured or refined for sale that implements a certified capability class that can be certified. It may be hardware or software or both.
Product Vendor	Product Vendors create personal healthcare devices.
Scheme Access	The criteria for access of conformity assessment bodies to the scheme and for the access of clients to the scheme.
Specification	A set of documented requirements to be satisfied by a material, design,

	product, or service.
Standard	Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or processes.
Statement of Compliance	Evidence of Continua conformity provided by the vendor self-declaring compliance to the CDG.
Subject Matter Expert	A person with a deep understanding of a specific process, function, technology or otherwise a recognized authority in a particular area or topic.
Summary Test Report	A top level statement clearly communicating the functionality that has been assessed successfully. Otherwise known as a declaration statement.
Syntactic Interoperability	Agreed to definition of the exact format of the information to be exchanged in terms of grammar, format and representation model. Also known as Technical Interoperability.
Test and Certification Plan	Describes the high level testing approach, resources (hardware, software), schedule, and features to be tested. The IEEE 829 Software Test Plan template was used as a basis for this plan. This document includes the test plan for the PHD interface as well as the Health Information System (HIS) interface.
Test Case	The smallest unit of testing performed during conformity assessment. A test case may consist of many steps, but success or failure is only reported on the level of a complete test case. The Continua Test Tool automates the execution of Test Cases. Per IEEE 610: A set of test scripts including values, execution pre-conditions, expected results and execution post-conditions, developed for a particular objective or test condition, such as to exercise a particular program path or to verify compliance with a specific requirement.
Test Case Database	A database that contains standards-based test cases (i.e. testable items list) and a mechanism to generate a Test Procedure for each device based on the specific features and functions it supports and assessment requested.
Test Case Matrix	The test case matrix is used to identify and convey the specific test cases to be executed during the conformity assessment testing process. The matrix contains information regarding the test case source, category, and the test platforms that have been validated to perform the test case correctly.
Test Description	A document that details the background, approach, procedure and possible results for a test. A Test Spec is an aggregation of Test Descriptions.
Test Implementation	An implementation of the testing algorithm described in a Test Description. It is contained in an automated test tool or defined via manual steps.
Test Management Tool	A tool that provides support to the test management and controls part of a test process. It often has several capabilities, such as testware management, scheduling of tests, logging of results, progress tracking, incident management and test reporting.
Test Method	A definitive procedure that produces a test result using a combination of test cases, procedures, test data references, and test tools.
Test Plan	Details the specific test cases required to assess conformity to specific industry standards and specifications.
Test Platform	A complete test system, which may be a combination of HW, SW and firmware, that implements test cases.
Test Procedure (Test Purpose)	A step-by-step implementation of a Test Specification contained in an automated test tool or defined via manual steps. By way of example: Test Suite Structure & Test Purposes for a particular feature (e.g. Device Specialization: Weighing Scale) within a functional area (e.g. PHD

	Interface).
Test Report	A statement of the results of each test or series of tests carried out in accordance with any specific instructions in the test scripts, including all information necessary for the interpretation of test results and all information required by the script used.
Test Scripts	Test procedures that describe the sequence of actions for the execution of given Test Procedure.
Test Specification	A collection of Test Procedures (e.g. TSS&TP) for a particular functional area (e.g. PHD Interface, Services Interface, HIS Interface) including details the background, approach, procedure and possible results for a test. A Test Spec is an aggregation of Test Descriptions.
Test Suite / Test Tool	An automated implementation of one or more Test Procedures.
Testable Item	Devices are tested for conformity against requirement statements in the standard. These statements are often identified by the word ‘must’ or ‘shall’. Each testable item must be covered in a test specification in order for the testing program to be considered complete.
Web Certification Interface	A series of interactive web pages that allow vendors to perform and monitor their devices progress through the certification process.

Step 1 Application For Certification

The Certification Application can be found on the Continua Certification Web Site (https://members.pchalliance.org/wg/members/document/234). To gain certification a company must be a member in good standing.

The application for certification will require the vendor to fill out general information about their device. It will also request that the user select which Certified Capabilities Class(es) apply to their device. For each Certified Capabilities class the applicant will be referred to a section of the Certification Specification. This specification has additional rules and requirements for certification of specific device classes. The Certification Specification may call for additional information to be attached to the certification application. This additional information might include certificates of certification from other SDOs, documentation of technical changes, parts lists, or design documents.

A part of the application form will require the applicant to answer a series of technical questions about their device. This series of questions is cumulatively known as the Device Profile Implementation Conformance Statements (PICS). The PICS is a survey of features implemented on a device.

The Device PICS contain enough information to determine the features of the specifications that applies to the SUT. The PICS are used by the test lab and the Certification Administrator to determine which test suites need to be run for certification. The mapping of features to test suites is described in the Certification Specification.

Types of Certification

Continua's goal is to provide a certification process that provides the testing of all Continua devices as defined in this document, while making sure certification is as simple as possible for vendors.

Continua recognizes four types of applications for certification. Each type of certification has a slightly different procedure and is subject to a different certification fee.

Type A Certification is for New Products that have not gone through certification before. This is the most extensive certification procedure. The device must run through the entire procedure described in the Certification Specification.

Devices that have been previously certified but have changes or additions not permitted by the allowed modifications defined in the Certification Specification are considered new products, even if the product was derived from a pre-existing certified product.

Multi-Type A Certification is identical to a Type A above but also enables two or more member companies to certify the same product within their own company name and saving the companies the cost of multiple test lab fees.

Type D Certification, also known as **Derivative Certification**, applies to products that are related to a product that has already been certified. They could be different products in a company's product line, or they could be the same product with bug fixes or feature enhancements. These devices need to go through a subset of the full certification process. The subset could be very small (a few tests) or large (the full transport test suite). Whether these tests are run by the manufacturer or by a Continua test lab is defined in the Certification Specifications.

If a device contains changes or additions allowed in the Certification Specification, then the device is eligible for Type D certification.

Type O Certification is testing of products that have an existing Type A certification under the name of another company. Type O certification allows vendors to use products from an OEM who has gone through certification and still use the Continua logo. The testing will most likely be a subset of the Type A certification, consisting of items which may have changed by the customer facing company.

Type U Certification refers to an update to the currently held certification information. No testing is done for a Type U Certification. This type of certification applies to changes that do not affect Continua functionality, such as form factor changes.

Determining the Appropriate Application Type

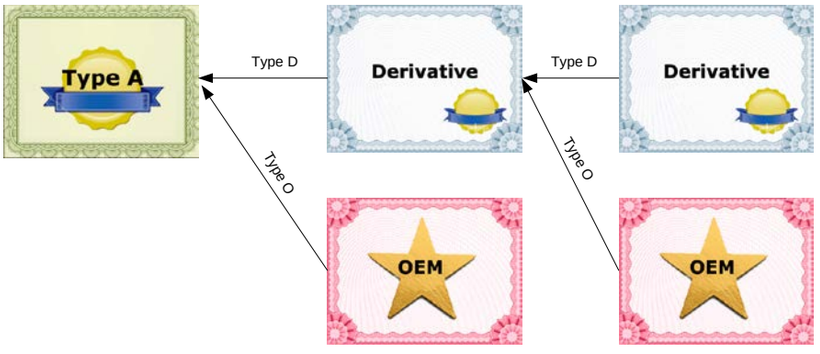
The decision as to whether a product related to an already certified product undergoes Type A, D, or U certification is determined by examining the scope of the change. The Certification Specification has the final authority in determining which types of changes warrant Type A and Type D certification; however, it is expected that the Certification Specification will utilize only those boxes with Xs in them below.

The table below maps changes to a product to the certification type allowed for that change. Note that in this table, Type O certification fits in the Type D or Type U certification for the change: Changes to Identifying Attributes.

	Type A	Type D	Type U
Changes to Identifying Attributes		X (if 11073-20601 attribute changes were made) Self-test should be allowed here	X (if no 11073-20601 attribute changes were made)
Change to Continua Software	X		
Add/Remove/Replace Continua Transport Interface	X		
Change Hardware Component	X (required if there is a change in the size/format of the data produced or the timing of the data produced)	X (may be required by class specific device certification specification)	X
OS Change	X (required if scope of change in OS may likely cause an interoperability or compliance failure in a device).	X (required if transport listing ID is changed)	X (if transport listing ID is not changed)
Addition or Removal of non-Continua Software Features		X (may be required by class specific device certification specification)	X (this is only needed if we change a feature tracked by the certification DB)

Relationship of Certifications

All Continua certifications are based off of a Type A certification. The other types of certificates will point back to the original Type A certification for the purpose of auditing and change tracking. Below is a diagram indicating the allowable relationships between Continua certifications types.



Cost of Certification

The cost of certification is based on two fees. The listing fee is paid to the license administrator who represents Continua. The testing fee is paid directly to the test house that conducts the testing. The timing of the payment of the testing fee is determined by the test house.

The listing fee covers the cost of processing the application which entails, verifying the registration information is correct, checking with other SDOs about existing certifications and resolving and disputes or testing issues with the device.

The testing fee is negotiated with the testing lab with maximum and suggested rates set by Continua.

Type of Certification		Description
New Products	Type A	Standard Certification for a New Device. Device must run through the entire procedure described in the Certification Specification.
	Multi-Type A	Identical to Type A above but enables two or more Member Companies to go through Certification for one device and share the test lab testing fee.
Derivative Products	Type D	Apply to products that are related to a product that has already been certified. Partial retest of a device for changes limited in scope to a component of the system.
OEM	Type O Derivative with PICS Changes	Re-label of a Continua Certified product by another manufacturer. New Continua features or device specializations were added. Further testing by Continua Test Lab was performed to verify compliance with the Certification Specification.
	Type O Derivative with no PICS Changes	Re-label of a Continua Certified product by another manufacturer. Technical changes were made but no new Continua features or device specializations were added. Further testing by Continua Test Lab was performed to verify compliance with the Certification Specification.
	Type O Informational changes only	Re-label of a Continua Certified product by another manufacturer. No technical changes to the product and no testing is required.
Update	Type U Additional Listing	An application to update identifying information related to the product. Member would like a new page showcasing the updated device. No re-testing is required by the Certification Specification.
	Type U Update Listing	An application to update identifying information related to the product. Member decides to replace existing listing with info showing the updated device No re-testing is required by the Certification Specification.

Step 2 Certification Administrator Processes the Application

New applications are processed by the Certification Administrator and the Technical Operations Manager via the CertAdmin@members.pchalliance.org mailing list. The Certification Administrator will verify the information in the test application is complete and correct, before clearing the application's status. The Certification Administrator will perform the following checklist before clearing the application:

a. Verify the Submitter is a Member in Good Standing
b. Check that CertAdmin has verified that all required fields of the application are correctly filled out with no obvious error
c. Verify that all information needed to verify SDO Certifications is attached and that the SDO certifications are valid

If the application is for a Derivative Certification (Type D), the Certification Administrator must additionally:

a. Verify that the vendor has referenced a Type A or Type D Certification.
b. Check that CertAdmin has verified that the vendor has documented the changes appropriately
c. Check that CertAdmin has verified that the vendor has correctly interpreted the derivative certification policies of the Certification Specification
d. Verify that re-test results and logs are attached if certification is a self-test.

If the application is for an OEM Certification (Type O), the Certification Administrator must verify:

a. Verify that the vendor has referenced a Type A or Type D Certification.
b. Check that CertAdmin has verified that all required fields of the application are correctly filled out with no obvious error
c. If the application is for a Certificate Update (Type U), the Certification Administrator must verify:
d. Verify that the vendor has updated the Certification Application with additional information.
e. Check if the vendor would like to update the current listing page, or add a new listing page.
f. Check that CertAdmin has verified that that all fields updated are clearly denoted with no obvious errors.
g. Verify that vendor has correctly set the date when the Type U changes can be communicated via the Continua web site.
h. Check that CertAdmin has verified that vendor has correctly interpreted the certificate update policies of the Certification Specification.

Step 3 Test Lab Receives the Application

A test lab is designated in the application for all Type A applications and Type D applications that require re-tests. The designated test lab will then be given access to the application and the information contained in it by Continua Administration after Continua Administration has verified that the Continua Administration and CertAdmin review of the Certification Application are both successful. Companies are responsible for providing a device for testing as which is as close to the finally production products as possible. Additionally the company must provide all documentation required to operate the device. It is the responsibility of the member company and the test lab to take care of all the logistics of shipping their device, getting reservations in Continua Test Labs and make appropriate payments towards testing costs.

The test lab will input the information contained in the certification application into the Test Tool for certification. This will implicitly test the technical accuracy of the certification application.

Vendors are also responsible for scheduling their testing with the Test Lab they would like to perform the testing at this time. The two steps required to hold a certification slot are that an application is received and approved and the Test Lab has confirmed the testing slot.

Step 4 Test Lab Conducts the Testing

The Test Lab will conduct the testing required by the Certification Specification and report the results back to the member company. A hands-off policy is adopted in the labs, once the certification starts, members cannot modify their firmware or hardware. One exception to this rule is when Vendors who have Continua Personal Health Gateways which contain a white list for regulatory reasons are required to remove the white list for certification testing. They will also be asked to put the white list in-place for a few certification tests as well as interoperability tests. Vendors may choose to bring two different machines to accomplish this task or to modify

the white list during testing. The test lab will carry out the test plan as described in the Certification Specification.

Much of the Test Labs operations and staffing is at the discretion of the Test Lab; however, Continua requires a set of vendor rights for Labs that wish to maintain their status as Official Continua Test Labs.

a. The test lab must have a test system in place for conducting test runs of the compliance test tool and for performing interoperability procedures. The system must guarantee that results are reliable, repeatable and that the procedure to reproduce an error is thoroughly documented.
b. The documentation must include all steps to reproduce the test procedure and must be available to the vendor and Continua on request such that the procedure can be disputed if believed to be deficient.
c. The test lab must provide a system for follow-up support for test results reported to the customer and Continua. The test lab must support follow-up questions related to the results and the procedures used to obtain the results.
d. The test labs record storage system must be able to support, test results, standards and test plan versions used at the time of testing, customer instructions, notes operating manuals, customer complaints or requests.
e. Continua members shall be granted the right to witness the certification being conducted on their device.

The Test Lab will conduct testing using the version of the Test Tool and interoperability procedures indicated by the vendor in the Certification Application assuming that version abides by the following guidelines. Continua recommends that this version be the latest version of the Certification Test Tool and interoperability procedures available. However, at the discretion of the member company a previous version of the Test Tool or interoperability procedures may be used for a period of 90 days after an updated version of the Certification Test Tool or interoperability procedures has been released. This allows the member company a buffer if they have been preparing for certification with a specific version of the test tool or interoperability procedures. The 90-day period applies to the time between the release of a new version of the Test Tool or interoperability procedures and the date certification testing begins. Vendors are not allowed to switch Test Tool or interoperability procedure versions in the middle of an already started certification pass. A certification pass with a specific version of a tool is complete when testing is successful, or within thirty days from the end of first round of testing, whichever comes first.

Note that this 90-day bridging period applies both to new maintenance releases of the Test Tool as well as completely new versions of the Test Tool. That is, after the v1.5 Test Tool is available, vendors will have 90 days during which they can certify using the v1.0 Test Tool or the v1.5 Test Tool. After the 90 days have completed, vendors must use the v1.5 Test Tool.

Step 5 and 6 Test Lab Reports Results to Continua member

When the Test Lab completes testing it will send all the test logs back to the Continua member. Companies are encouraged to store their test logs for future reference. If a device fails testing it may opt to make fixes to the product and arrange for retesting with the test lab. This is out of scope of Continua and test results should only be turned in to Continua Administration when the member company is satisfied with the test results produced by the test lab. It is the member's responsibility to formally request the Test Lab to submit the official test results to the Certification Administrator and CertAdmin. Upon prompting by the Test Lab, the vendor will request that the Test Lab formally submit their results in order to achieve Continua Certification. Member companies are free to pre-submit information to the CertAdmin or Certification Administrator if they would like additional assistance on waivers or have other questions.

The Test Lab results consist of a Test Report, which contains a summary listing the test cases that were executed and comments from the Test Lab. The Test Lab will comment on all INCONCLUSIVE and FAIL results in order to provide information to the CertAdmin to enable seamless processing of waiver applications. The Test Lab also maintains the XML or HTML format Test Logs in storage; however, these are not provided to the Continua member or Continua Administration or CertAdmin unless specifically requested.

Waiver Application

Continua requires that the test lab submit test results as generated by the Test Tool, even if the failures are caused by an error of the test tool or specification. For each test case that the device under test has failed an "Application for Test Case Waiver" must be submitted to the CertAdmin in order for the vendor to receive Continua Certification. Where a device has received an Inconclusive result, it is the test engineer's responsibility to drive

the verdict to either PASS or FAIL. Inconclusive Results may be due to the test tool not being able to determine the verdict so the test may need to be run manually in order to verify the result (an alternate approach to verify a PASS result is required). The test engineer shall work with either a CCE, a senior engineer or the test lab manager (not by him or herself alone) in this assessment. The test report shall show the history and reasoning for any decisions made by the test lab in documenting as a PASS verdict. Where an alternate approach is found, it is the CCEs responsibility to update the inconclusive spreadsheet.

Waivers are only applicable for an error in the Test Tool or in the Continua Design Guidelines or underlying standards/specifications. They cannot be used for a faulty device under test.

Vendors or Test Labs may submit waiver applications. In general, Test Labs will provide assistance, but vendors will submit the actual waiver application. Vendors are encouraged to review carefully all waivers being submitted by the Test Lab on their behalf. The waiver application will allow the Vendor, or test lab to indicate the issue and if they believe that the test tool, standards or test procedures are in error. Waivers are a normal part of the certification process and over time help to create better tests, standards and certification programs.

Step 5a Approving Waiver Applications

A device's certification will enter a hold status until all the applications for waivers have been processed. The Technical Operations Manager (CertAdmin) will be responsible for reviewing all applications and making a determination to dispatch the application as follows:

A. The Device Under Test is in error or implements the specifications differently than foreseen during specification development.

   First Step: CertAdmin will work with the member company and the test lab to help understand and document the reason for failure. If the CertAdmin determines that the reason for the failure or inability to complete the test is due to an unforeseen approach to compliance with the specifications, a waiver shall be provided and further evaluation of the test procedure and test tools to encompass the new approach to compliance will be assessed for necessary actions and updates.

   Escalation: The CertAdmin will assemble other domain experts in the area to help document and address the misunderstanding.

B. The Test Tool is in Error because it is incorrectly implemented or misinterprets the standard

   Error Resolution: CertAdmin will work with the test lab to help understand the reason for failure. CertAdmin will submit an issue into the Issue Tracking System.

   Escalation: In cases of a disagreement between the Test Tool vendor and the CertAdmin on correctness of the Test Tool. The CertAdmin will solicit documentation from other domain experts and a final decision will be made by the Certification Administrator.

   Certification Resolution: The vendor and or test lab must then provide proof of compliance consistent with the purpose of the test case through another means, such as manual testing, interoperability testing with a reference device, or a modified Test Tool. The device vendor will then receive a waiver for the test case and certification will be processed.

   The time limit for this process is seven days from start to finish.

C. The standard is ambiguous or in error causing invalid or contradictory test procedures.

   Error Resolution: CertAdmin will consult with domain experts to determine if an errata request should be submitted. IF so an errata request will be entered in the Continua Errata database. From the database they will be distributed to the appropriate Continua working group, or other standards body.

   Certification Resolution: The device under test will receive a waiver for the test case once the issue is marked Verified → Fixed in the bugzilla database and certification will be processed without the result. Note that in order for an issue to be marked Verified → Fixed in the bugzilla database, it must be redlined and approved by GTC (for Design Guidelines issues) or redlined by the SDO (for underlying standards/specifications issues).

Note that, if a vendor chooses, the waiver process can be begun prior to certification. That is, if the vendor believes that the Test Tool is in error or the standard is ambiguous, they can begin the process listed above in order to obtain their waivers prior to certification testing.

Steps 7 to 10 Payment of Listing Fee and Signing of Certification Mark License

The Certification Administrator will provide the member with a Certification Mark License Agreement and an invoice for the Continua listing fee. This is done after all certification testing issues have been resolved.

Note that a listing fee is required for each new web "listing" of a device. One listing corresponds to one web page on the Continua website. If a vendor chooses to replace an existing listing (For example, a Type D certification that replaces the previous Type A.), no listing fee is required. If a vendor has certified a device that contains two Continua Interfaces within one certification testing session (i.e., both a PAN Manager and WAN Sender are certified at a Continua test lab at the same time) only one listing fee shall apply. For Type U, if a vendor chooses to augment an existing listing, no listing fee is required. Vendor also has an option to create a new page showcasing the updated device, and there is a fee required. Type A and Type O changes always require a listing fee.

The Certification Mark License is a document describing the allowable uses of the Continua Certified logo, and it must be signed by all member companies once certification testing is complete.

The financial status of the Certification is tracked as part of the certification process. Once payment has cleared and the License has been completed and returned, the member is entitled to all the privileges of certification.

Verification List

The list below provides a summary of the items the Continua Administrator will verify prior to declaring a device is Continua Certified:

- Member company is in good standing with Continua.
- Official test lab results (signed, from Test Lab) have been received.
- Approved Waivers from CertAdmin, if any, have been received.
- Transport Certification obtained and referenced in the Certification Application.
- Completed Certification Application has been received, and the CertAdmin has verified it is complete.
- Signed Certification Mark License Agreement has been received.
- Signed Reference Device License Agreement has been received.
- Listing Fee (if applicable) has been paid.

Prior to publishing vendor information in the Certified Product's Showcase, the CertAdmin will verify that the information and given name of the product are accurate. Specifically, the CertAdmin will check that the product name:

- Does not list support for a device specialization or functionality that isn't Continua Certified (ex. Body Composition Monitor for a Weighing Scale, or Weighing Scale for a Thermometer, or Bluetooth if only certified for USB).
- Does not imply support for more than what is Continua Certified (ex. Continua Manager for a device that does only Weighing Scale Manager functionality).
- Does not imply support for less than was certified (ex. Bluetooth Stack instead of Continua Bluetooth Manager).
- Lists the transport(s) utilized.
- Lists all the device specializations supported.

Steps 10 and 11 Enjoy Certified Product Privileges

A vendor may now use the Continua logo and messaging as specified by the Logo usage guide. At this time, this product from the member company will be listed in Continua's Certified Products Showcase and listed as a Continua certified product. The Certification is valid, as long as the company remains a member in good standing of Continua, for the lifetime of the product and subject to the configuration remaining unmodified. A printable and downloadable Certificate will be available via the Web Certification System.

As a privilege of certification, Continua members may choose to participate in Continua's product marketing program by donating a device for use at Continua Plugfests and during Continua sponsored events. Members will also be asked to submit a photo and description of the Certified product for Continua marketing purposes.

Annex B – TCC Individual Roles & Responsibilities

The following section describes roles and responsibilities for TCC individuals and entities. The individuals include:

1. TCC chair – The TCC chair oversees all TCC activities and facilitates strategic decisions on TCC scope, TCC resources and TCC roles. The TCC chair is responsible for ensuring all aspects of TCC run smoothly and roadblocks are removed.
2. Certification Administrator (CertAdmin) – The CertAdmin is responsible for:
   - Technical Consulting
   - Guideline Advice and Maintenance
   - Management of suppliers (e.g., Tool vendor, Test Labs) with the Test Administrator
   - Development of RFPs and responses as requested with the Test Administrator
   - Implementation of Conformance and Interoperability Program
   - Operation and Support of Certification/logo Program
   - Plugfest Support
   - Global Technical Committee Support
   - Liaison to Standards Organizations and other Industry Associations
   - Technical Communications.
3. CESL Control Board – The CESL Control Board is in charge of controlling changes to the CESL code base. These changes include decisions on when to implement major API changes and add new modules. The CESL control board must also approve any major architectural change to the CESL source code. The control board is comprised of a representative from the company maintaining the CESL code base and at least one representative from the TCC and one representative from the GTC. The CESL control board is a subcommittee of the TCC.
4. Certification Oversight Committee – A certification oversight committee is a group of representatives from the GTC and TCC. It is assembled by the TOM to assist in resolving issues that arise relative to certification. In the case where the certifying vendor contests results from a test lab or contests the type of certification assigned to their product, the TOM will attempt to broker a resolution by clarifying technical or procedural aspects of the certification program. If the TOM can not broker a mutually agreed to resolution, they will assemble a group of three or more neutral parties with domain experience in the area of conflict to make a decision on the issue.
5. TCC test labs – The TCC test labs are responsible for running the tests which guarantee compliance to Continua Design Guidelines. These results are then sent to the Continua TCC Test Administrator for review and administration of the logo.
6. GTC liaisons – The GTC liaisons are responsible for bringing GTC schedule and deliverable information to the TCC as necessary. They may also answer questions on GTC architecture and vision. Any TCC member that is also a member of GTC is an honorary “GTC liaison.”
7. Test Tool Vendor – The test tool vendor is responsible for creating the mostly automated test suite that will be run by test labs to verify compliance.
8. Test Administrator- The TCC Test Administrator is responsible for:
   - Program Management (schedule, mtgs, reports, issues)
   - Execute Certification Program (questions, company interactions, records, logo)
   - Manage suppliers (e.g., Tool vendor, Test Labs) with the CertAdmin
   - Develop RFPs and responses as requested with the CertAdmin
   - Manage Certification Program Website (listing, processes)
   - Manage Device Showcase website

The entities include:

1. TCC – Continua's Test and Certification Committee, responsible for the overall process, from definition to implementation, of testing and certifying Continua devices.
2. GTC – Continua's Global Technical Committee, responsible for the architecture, requirements, and interoperability guidelines needed to implement a Continua device.
3. MAWG – Continua's Market Adoption Working Group, responsible for defining Continua's brand and making it well-recognized and well-respected in the marketplace. Also responsible for logo requirements and guidelines.