



Continua®

CONTINUA COMPLIANT a Self-Declaration Process by Continua

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Abstract

This Continua Compliant Self-Declaration Process provides a top-level overview of the procedures to be used by vendors to self-declare directly to its customer their product compliance to the Continua Design Guidelines. The PCHAlliance makes no representations of compliance.



Summary

This Continua Compliant Self-Declaration Process provides an overview of the objectives, representation, accreditation, declaration, procedures, publicity, marks and maintenance associated with vendor self-declaration of compliance to the Continua Design Guidelines (CDG) [1].

The Conformity Assessment Scheme (CAS) by Continua [2] defines the processes and procedures used to develop test plans and supporting specifications, the uniform rules by which the testing 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.

The Conformity Assessment Test Plan (CATP) by Continua [3] provides a top-level overview of the test specifications and test profiles used to verify product conformance to the Continua Design Guidelines. It outlines the scope of the conformance and interoperability tests, test suite structures & test purposes, test case reference list, and the Continua Test Tool.

Vendors seeking to self-declare compliance to the CDG must demonstrate this compliance by executing all applicable tests as defined in the CATP using the publicly available Continua Test Tool (CTT) [4].

The objective of this process is to provide a freely available uniform pre-approval procedure enabling any vendor the ability to self-declare directly to its customer that its products are compliant to a specific version of the Continua Design Guidelines. Other than making this process and CTT available to the vendor, the PCHAlliance makes no other representations as to the state of product compliance.

Test applicability and pass/fail criteria, and the Continua Test Tool used for compliance test execution, are the same for both this Continua Compliant Self-Declaration Process and for Continua Certification. Whereas Continua Certification tests must be executed by a qualified 3rd party in an ISO 17025 accredited laboratory, Continua Compliant testing may be executed by the product vendor in it's own laboratory. It is recommended that laboratories used to conduct Continua Compliant testing be accredited to ISO 17025 or otherwise employ quality processes to the intent of ISO 17025.

A Statement of Compliance generated by the Continua Test Tool following successful testing of the product may be presented directly to the customer without review or approval of the PCHAlliance. The vendor has the option of posting their Continua Compliant product on the PCHAlliance website.

History

This is the first release of the Continua Compliant Self-Declaration Process.

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Continua Compliant Self-Declaration Process

Purpose and Application

Purpose

The purpose of this Continua Compliant Self-Declaration Process is to provide an overview of the testing and reporting procedures that are performed to demonstrate and self-declare that products are compliant to the Continua Design Guidelines and, optionally, interoperable with other Continua Compliant products.

1 Application

This document familiarizes the reader with an overview of the objectives, representation, accreditation, declaration, procedures, publicity, marks and maintenance associated with vendor self-declaration of compliance to the Continua Design Guidelines.

2 Precedence

In the event of conflict with the CAS by Continua or CATP by Continua specifications, this Continua Compliant Self-Declaration Process takes precedence.

3 Objectives

The objective of this procedure is 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 is of sufficient rigor 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 (such as medical technology, pharmaceutical and system integration companies) to use as a method to promote their product to the industry. A public listing helps potential customers see products that can work within the Continua ecosystem. This self-declaration process also lowers the barrier for customers who may be unable or unwilling to require 3rd party certification [5].

4 Representation

It is important to note that self-declaration of compliance is governed by the business arrangements between the product vendor and the customer 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 statement. Products that successfully complete this declaration of compliance process will be listed on a PCHAlliance public web site. The PCHAlliance makes no other representations.

5 Accreditation

It is recommended, but not required, that laboratories conducting conformity assessment testing for the express purpose of self-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 and continue to maintain a quality management process and have the requisite domain expertise is preferred.

5.1 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 customer. Key personnel that have an involvement or influence on the testing activities should be identified to avoid any potential conflicts of interest. Buyers are encouraged to verify that vendors' quality processes meet their requirements.

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.

5.2 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.

6 Declaration

Entities self-declaring their compliance to the CDG must meet the following criteria.

6.1 Criteria

All compliance assessment criteria appropriate for the features supported by the product under test are the same regardless of pursuing certification or self-declaration. This is assured through the PICS/PIXIT procedure integral to the CTT. See CTT User Manual for more information [6].

6.2 Test Platform

The product vendor shall use the latest version of the CTT [4]. Alternatively, the vendor may use the immediate previous version of the CTT up to 90 days following the latest release.

6.3 Test Plan

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.

6.4 Records Retention

Vendors self-declaring their compliance to the CDG shall retain records of test results for the life of the product design that was declared compliant. Test results will be made available to customers upon their request.

6.5 Statement of Compliance

The Statement of Compliance is evidence of compliance to a specific version of the CDG 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. Please contact [PCHAlliance](#) for account to access Bugzilla for tracking issue resolution. [CCEs](#) are available for assistance.

The CTT provides a declaration statement that defines exactly which features or capabilities 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. See Appendix for Statement of Compliance template.

7 Procedures

Continua provides a series of procedures in sufficient detail for vendors to navigate the test and self-declaration process. Continua Certified Experts (CCEs) are available for assistance. [8]

7.1 Applicable Documents

It is recommended that the vendor familiarize themselves with the following documentation prior to testing:

- Conformity Assessment Scheme (CAS) by Continua [2]
- Conformity Assessment Test Plan (CATP) by Continua [3]
- Continua Conformity Assessment Web Site [5]
- Continua Test Tool User Manual [6]
- Continua Test Tool Installation Guide [7]

7.2 Download Continua Test Tool

The Continua Test Tool Installation Guide describes the installation procedure for the Continua Test Tool software and the drivers that are necessary to execute the test cases.

7.3 Execute Compliance Testing

The Continua Test Tool User Manual provides a detailed description of the usage and features of the Continua Test Tool. It guides the test operator through all the steps: parameters, test execution, results and the process by which to generate the self-declaration statement. In brief the steps are:

7.3.1 CREATE New Project & Choose Template

Create a Project to define PICS, PIXIT and general parameters values. There are a number of templates available to quickly set up the more common test projects (e.g. Blood Pressure Monitor BTLE).

7.3.2 LOAD Project

Click LOAD to generate a baseline of all tests that may apply for each supported transport and interface.

7.3.3 EDIT PICS

Use PICS Editor to establish the applicability conditions for a Test Case. Static Conformance Review is performed automatically to ensure configuration is valid.

7.3.4 EDIT PIXIT

Use PIXIT Editor to provide additional information about the Product Under Test (PUT). This information is necessary for testing purpose. Its answer can be a number, a string... Test Tool uses this information to execute the Test Case or to check it with PUT responses.

7.3.5 EDIT General Parameters

Before executing the test case, some parameters related to the Test Tool must be properly configured (e.g. waiting time to allow pairing process). Non-relevant parameters for the selected PUT appear disabled.

7.3.6 EDIT Test Cases

The tool dynamically selects applicable test cases based on PICS values. Add or subtract tests as appropriate.

7.3.7 EXECUTE

Once test cases have been selected, press EXECUTE to open the sequencer to observe session progress and trace logs. User has the options to Run, Stop, Restart and Exit the test process. Trace logs are available to help troubleshoot. Logs may be exported to support Continua Certification but are not exportable for Continua Compliant testing.

7.3.8 RESOLVE FAIL and INCONC

After executing a test case, three possible test case results or verdict can be obtained:

- **PASS**, if everything is correct.
- **FAIL**, if the test case result is not correct.
- **INCONC** (inconclusive). This result is obtained if some failure has been produced during the execution and Test Tool can not check what it has to test.

All tests must result in PASS (or be allowed via waiver) in order to self-declare compliance or apply for certification.

7.4 Execute Interoperability Testing (Optional)

In addition to compliance testing using the CTT, interoperability testing either in the lab against other Continua Compliant products or at a Plugfest against other vendor products is encouraged. This demonstrates the ability to communicate and share data with a variety of components in an unambiguous and predictable manner to exchange data accurately, effectively, and consistently. See CATP by Continua (Section 6) for more information on Interoperability Testing. See the Continua Conformity Assessment web site [5] for more information on Plugfests.

7.5 Statement of Compliance

The Statement of Compliance generated by the Continua Test Tool provides a clear and concise statement as to which capability classes the product is compliant. PCHAlliance strongly encourages this statement be presented to the customer as part of the vendor's self-declaration of compliance. However, such declarations are governed in whole by the business arrangements between the product vendor and the customer. In brief the steps to generate a Statement of Compliance are:

7.5.1 SELECT Continua Compliant Self-Declaration Statement

Upon successful completion of testing, select the “Continua Compliant Self-Declaration Statement” option.

7.5.2 COMPLETE Application

Complete the 3-step process to generate a Continua Compliant Self-Declaration Statement.

1. Product Overview – provide company and product information to be included in the statement
2. Contact Information – provide contact information for individual and company address.
3. Generate PDF – provide name, title and signature of individual authorized to represent the company self-declaring compliance.

7.5.3 GENERATE Self-Declaration Statement

A single page Continua Compliance Self-Declaration Statement is generated that defines exactly which features, capabilities and configurations were determined to be Continua Compliant. The Statement of Compliance must be signed by an authorized representative of the vendor who conducted the Continua Compliant testing.

7.5.4 PRESENT Continua Compliant Self-Declaration Statement to Customer

The Continua Compliance Self-Declaration Statement generated by the Continua Test Tool following successful testing of the product may be presented directly to the customer without review or approval of the PCHAlliance.

7.6 Posting to Continua Compliant Products Listing (Optional)

The vendor is encouraged to list their Continua Compliant product on the Continua Compliant Products Listing web site [9] to enable discovery of such products while increasing their availability and awareness in the marketplace.

8 Publicity

Vendor’s self-declaring compliance to the CDG shall make this declaration public information. The Statement of Compliance shall include a date on which the declaration may be made public by PCHAlliance and, at its sole discretion, post this information on the PCHAlliance web site. If no such date is provided, then PCHAlliance may post the declaration once the product is known publicly. 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. [2]

9 Marks

Vendor’s self-declaring compliance of a product or service to the CDG may use the “Continua Compliant” word mark but shall not display the Continua Certification logo in reference to the product or service. The Continua Certification Logo is reserved for those products successfully completing the [Continua Certification](#) process.

10 Self-Declaration Maintenance

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

A. Appendices

1 Statement of Compliance Template



CONTINUA COMPLIANT SELF-DECLARATION STATEMENT

The undersigned hereby declares that this product has successfully passed the Continua Compliance Self-Declaration Process with the features, capabilities and configurations listed below per the Conformity Assessment Test Plan as administered by the Continua Test Tool.

Product Overview	
Company Name	<company name>
Product Name	<product name>
Model Number	<model number>
Hardware Version	<hardware version>
Software Version	<software version>
Product Role	<declared capability>
Transport Type	<transport type>
Declaration Date	<date>
Guidelines Version	<CDG version>
Continua Test Tool Version	<CTT version>
Company URL	<company url>
Product URL	<product url>
Not to be made public by PCHAlliance before:	<date>

Compliance Declarations

- <capability A>
- <capability B>
- <capability C>

 <authorized agent name>
 <authorized agent title>
 <declaring company>



2 References

- [1] Continua Design Guidelines.
<http://www.pchalliance.org/continua-design-guidelines>
- [2] CAS by Continua
<https://members.pchalliance.org/document/dl/1185>
- [3] CATP by Continua
<https://members.pchalliance.org/document/dl/1221>
- [4] Continua Test Tool.
<https://members.pchalliance.org/document/dl/1324>
- [5] Continua Conformity Assessment Web Site
<http://www.pchalliance.org/continua-conformity-assessment>
- [6] CTT User Manual
Included in CTT Download
- [7] CTT Installation Guide
Included in CTT Download
- [8] Continua Certified Experts
<http://www.pchalliance.org/continua-certified-experts-cce>
- [9] Continua Compliant Products Listing
<http://www.pchalliance.org/continua-compliant-products>

3 Abbreviations

CAS	Conformity Assessment Scheme
CATP	Conformity Assessment Test Plan
CCE	Continua Certified Experts
CDG	Continua Design Guidelines
CTT	Continua Test Tool
PCHAlliance	Personal Connected Health Alliance
PICS	Protocol Implementation Conformance Statement
PIXIT	Protocol Implementation eXtra Information for Testing
PUT	Product Under Test
SCR	Static Conformance Report

4 Glossary

Accreditation	Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.
Certification	The process by which the TCC certification body verifies, through conformance 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.

Capability Class	Entity in the Continua E2E Architecture for which a complete set of guidelines has been defined such that a device or application can demonstrate compliance with that set of guidelines via the Continua Certification or Continua Compliant program.
Continua Compliant	The state of being in accordance with Continua Design Guidelines and specifications. Compliance with Continua Design Guidelines and specifications will be assessed through conformance testing performed per the Continua Certification or Continua Compliant process.
Test and Certification Committee (TCC)	The Test and Certification Committee oversees development of all products and services essential to support test & certification of products pursuing compliance with the Continua Design Guidelines. It is open to all members and is composed primarily of engineers from member companies with expertise in healthcare IT products and device certification schemes applicable on a global scale
Self-Declaration	First-party attestation
Statement of Compliance	A document generated by the Continua Test Tool affirming that, at the time of assessment, the product successfully passed all conformance tests demonstrating its compliance with the indicated capability class of the CDG.