DELIVERABLE

D5.10 –Guidelines for the UNCAP certification suite - first version

Project Acronym: UNCAP

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Authors: Scott Cadzow (C3L), Martin Ford, Lynn Calder (GiSt)

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P	Public	**X**
C	Confidential, only for members of the consortium and the Commission Services	

1. Revision history and statement of originality

1.1. Revision history

Rev	Date	Author	Organization	Description
0.1	0-12-16	Scott Cadzow	C3L	Initial text and ToC
0.2	18-12-16	Scott Cadzow	C3L	Refinement of CE marking issues
0.3	21-12-16	Martin Ford, Lynn Calder	GiSt	Refinement of deliverable
0.4	22-12-16	Irene Facchin	TRILOGIS	Quality check
1.0	23-12-16	Giuseppe Conti	TRILOGIS	Final review

1.2. Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both. In particular, some of *the content of this document has been taken from contributions made by C3L to ETSI. Where material has been published elsewhere it has been clearly referenced. Note however that material may have been submitted to ETSI as contributions to meetings and not subsequently published. In such cases the contributions are referenced but may not be visible to non-members of ETSI.*

2. List of references

Number	Full Reference
1	*Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC Text with EEA relevance*
2	*UNCAP Deliverable D2.4*
3	*Directive 2007/47/EC*
4	*Giuseppe Conti, Leonardo Plotegher, Fabio Roncato and Claudio Eccher (2016). AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile - OGC Discussion Paper. Available for download from http://www.opengeospatial.org/docs/discussion-papers*

3. Table of Acronyms

Acronym	Description
RED	*Radio Equipment Directive*
R&TTE	*Radio and Telecommunications Terminal Equipment*

4. Introduction and overall rationale

The UNCAP certification suite does not give any indication of conformance to legal requirements for placing a product or service on the market. The certificate offered allows the UNCAP eco-system to recognise UNCAP devices on the broad assumption that relevant legal requirements have been met. The role of standardization and conformance with those standards for UNCAP products and services is outside the scope of the present document.

This document collects the body of standards that will be then used to implement the certification services during the last part of the project. The underlying principle has been to isolate the corpus of standards that will have to be used as baseline to ensure compliancy of new components of UNCAP, to be carried on by external third parties, in addition to those already developed by the consortium members.

It should be noted that the present document does give an indication of the relevant tests and obligations to be met for UNCAP equipment to be placed on the market.

5. Executive Abstract

This is one of two deliverables, the first deliverable which is a draft for 2016 and the final version will be released in 2017.

As has been stated in D2.4 the **UNCAP certification suite** is a part of the UNCAP set of products which is to be implemented, with particular regard to the software development, according to the guidelines identified in the this report. The UNCAP certification suite is going to be developed as a part of the UNCAP website (http://www.uncap.eu) that provides guidelines, to help further hardware or sensor manufacturers test compliancy of their solutions to the standards supported by UNCAP, and those standards required to place a product on the market.

It should be noted that the present document distinguishes those standards required for market access in Europe (broadly grouped under the CE marking requirements), and those standards for data modelling and interoperability required by the UNCAP model and which will have to be used as guidelines for the implementation of the certification suite.

The purpose of this report is to assist UNCAP partners and associated stakeholders in meeting their market obligations.

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7. Market access conformance

7.1. Electrical safety standards (low voltage directive)

The Radio Equipment Directive, EU 2014/53/EU, substantially modifies the steps required by a manufacturer to place equipment containing the ability to transmit or receive radio signals. The directive clearly states that "*all economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market radio equipment which is in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain*". UNCAP has to take responsibility and within UNCAP individual technical partners have to take responsibility for the equipment (including software) that they provide.

7.2. Radio equipment standards (Radio Equipment Directive)

7.2.1. Overview of RED

To give an overview of RED it is possibly best to start with the outline of RED given by ETSI's experts and posted on the ETSI web page: http://www.etsi.org/technologies-clusters/technologies/regulation-legislation/red.

It is quite important to compare and contrast with the preceding R&TTE directive as the bulk of understanding of the market to date has been bound up with the market interpretation of the R&TTE directive that is being replaced by RED. The RED applies to equipment that is placed on the market (this contrasts with the R&TTED, which also applied to "relevant components" of radio equipment).

This is important - this means that equipment connecting by Bluetooth or WiFi (IEEE 802.11) or any other wireless (radio) capability is covered, not just the radio module.

- The RED applies to equipment which intentionally transmits or receives radio waves for communications or radio determination, regardless of its primary function. For example, a "connected" device that uses an embedded radio module for communications or to determine its position to meet the same radio requirements as a purpose-built radio equipment.
- Wired telecommunications terminal equipment that does not function using radio is not covered by the RED.
- Radio equipment covered by the RED is not subject to the Low-Voltage Directive (LVD) or the Electromagnetic Compatibility Directive (EMCD): the essential requirements of those Directives are covered by the essential requirements of the RED, with certain modifications.
- The RED places additional emphasis on efficient and effective use of the spectrum. For example, radio equipment needs to demonstrate the performance of its receiver part, as well as its transmitter, as both are considered to affect the efficient and effective use of the spectrum.
- The RED applies to radio equipment operating at frequencies below 3 000 GHz, including radio equipment operating below 9 kHz that is not covered by the R&TTED or by National frequency regulations.

- The RED also applies to radio determination equipment: equipment that uses the propagation qualities of radio waves to determine its position.
- The R&TTED specifically excluded Broadcast TV & radio receivers from its scope. These are now specifically included in the scope of the RED.

7.3. Medical equipment standards (Medical equipment directive)

A medical device is one that is classified as such and marked, in the EU, by an appropriate CE mark. Very simply a Medical Device (from Directive 2007/47/EC []) means: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
- and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.

In contrast any other device, such as a fitness oriented Heart Rate Monitor (HRM), can only be used for indicative information and is specifically excluded from use in any form of diagnosis, monitoring, treatment or alleviation.

7.3.1. Definition of medical equipment within UNCAP

The following types of equipment have been identified as interacting with the UNCAP system:

- Blood Pressure Monitor,
- Heart Rate Monitor,
- Oximeter,
- Scale (weighing measure for patients),
- Glucometer.

7.3.2. Relevant Harmonized Standards

Some of the following standards may have to be complied with by manufacturers of medical equipment interacting with UNCAP. Each manufacturer (of software, hardware or as system integrator) should seek advice specific to their product or service to assure themselves of compliance. As a project UNCAP does not take responsibility for assertions of compliance as compliance is a general requirement of market access.

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

It should be noted however that there are no specific European standards (EN) for Oximeters, Glucometers, or weighing scales, although a number of general harmonized standards have to be complied with:

- EN 60601-2-27:2006: Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment,
- EN 1041:2008: Information supplied by the manufacturer of medical devices,
- EN 980:2008: Symbols for use in the labelling of medical devices,
- EN 1060-3:1997+A2:2009: Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems,
- EN 1060-4:2004: Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers,
- EN ISO 10993-1:2009: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)
- EN ISO 13485:2012: Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003),
- EN ISO 16201:2006: Technical aids for disabled persons - Environmental control systems for daily living (ISO 16201:2006),
- EN ISO 81060-1:2012: Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007),
- EN 60601-1-6:2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability,
- EN 60601-1-8:2007: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems,
- EN 60601-1-11:2010: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment,
- EN 60601-2-26:2003: Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs,
- EN 62304:2006: Medical device software - Software life-cycle processes.

7.3.3. Software conformance requirements

Where software is an integral element of a medical device it should be assessed as an integral element. However, EN 62304 applies to the software life-cycle.

Where a software revision is made to a device any alteration of functionality may require that the device is re-assessed and re-certified. Market surveillance authorities will be able to assist.

8. UNCAP internal development standards

8.1. Data transfer representation standard

Data internally to UNCAP shall be described using JavaScript Object Notation (JSON) and transferred as JSON objects over HTTP or equivalent transfer protocols.

There is no formal conformance test suite for JSON.

Although JSON is formally prepared by the JSON group and formally standardised by ECMA as ECMA-404 as an extension of ECMA-232 (JavaScript), and by the IETF in RFC7159, the standards are not recognised or cited by the Official Journal.

As JSON is self-certified, the use of JSON does not infer or imply any degree of interoperability, for example, the representation of a blood-pressure reading from Manufacturer A does not need to be recognised by Manufacturer B.

Internally, the UNCAP data dictionary is maintained by Trilogis and conformance is determined by code acceptance test, referred to as the UNCAP certification suite, to be developed under responsibility of partner FIDA.

8.2. User interface style guidelines

8.2.1. Administration interfaces

There are no formal conformance requirements for UNCAP although the guidelines given in 102.2.2 (below) shall apply.

8.2.2. User interfaces

While there are no harmonized standards it is noted that Annex I of the Medical Devices Directive 93/42/EC (MDD) and Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) establish the essential requirements of medical devices, to ensure adequate safety and performance. In 2010, Directive 2007/47/EC [6] amended the MDD and Recital 18 provided the background to the introduction of more specific ergonomic requirements into the MDD, specifically:

- ER 1. reducing, as far as possible, the risk of use error due to the **ergonomic features** of the device and the environment in which the device is intended to be used (design for patient safety),
- ER 9.2 the risk of injury, in connection with their physical features, including the volume and pressure ratio, dimensional and where appropriate **ergonomic features**,
- ER 10.2 The measurement, monitoring and display scale must be designed in line with **ergonomic principles**, taking account of the intended purpose of the device,
- ER 13.1 Each device must be accompanied by the information needed to use it **safely and properly**, taking account of the training and knowledge of the potential users, and to identify the manufacturer,
- Other ERs that may be affected to some degree by ergonomics include 2, 3, 6, 12.8, and 12.9.

Pending the ratification of tests for compliance to the essential requirements of MDD, each UNCAP partner responsible for provision of a user interface shall provide documentary evidence of how each of the essential requirements have been met.

8.3. Data model

The most relevant aspect of the overall standardisation suite regards the internal data model which has been formalised within a comprehensive data model referred to as AHA-ML. The rationale behind the creation of what has been referred to AHA-ML (Active and Healthy Aging Mark-up Language) is to create a common data model of facilitate the exchange of information describing observation acts and their results data regarding psychophysical conditions.

The specification of AHA-ML, which have been included as annex in the following pages, have been defined within a comprehensive discussion paper presented at the Open Geospatial Consortium, publicly available for download from the OGC portal under document number 15-116 [4].

The content of discussion paper has been used to officially submit through the health Domain Working Group of the Open Geospatial Consortium (OGC) for the creation of a dedicated standard working group, as reported in D.5.8 – Contributions to standardization - second year report.

9. Annex 1: AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile - Discussion Paper

Initial note: the official motion by OGC for Approval of the following document titled "AHA-ML (Active and Healthy Ageing Mark-up Language) an O&M profile" as an OGC Discussion Paper was passed by the OGC Technical Committee (TC) with no objection to unanimous consent in early 2016 during the 98th OGC TC Meeting [4].