DELIVERABLE

D.5.11 – Guidelines for the UNCAP certification suite - second version

Project Acronym: UNCAP

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Dissemination Level		
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	November 2017	Scott Cadzow	C3L	Structure, text for market access conformance requirement
0.2	December 2017	Scott Cadzow	C3L	Finalisation
0.3	22.12.2017	Giuseppe Conti	TRILOGIS	Final review
0.4	28.12.2017	Irene Facchin	TRILOGIS	Quality check

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This deliverable contains original unpublished work except where clearly indicated otherwise.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
AHA-ML	*Active and Healthy Ageing Mark-up Language*
AIMDD	Active Implantable Medical Devices Directive
APK	*Android Package Kit*
CE	*CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)*
ECMA	*European Computer Manufacturers Association*
EMCD	*Electromagnetic Compatibility Directive*
EN	*European Norms (standards)*
ER	*Essential Requirements*
ETSI	*European Telecommunications Standards Institute*
GPSD	*General Product Safety Directive*
IEEE	*Institute of Electrical and Electronics Engineers*
IETF	*Internet Engineering Task Force*
ISO	*International Organization for Standardization*
JSON	*JavaScript Object Notation*
LVD	*Low Voltage Directive*
MDD	*Medical Devices Directive*
R&TTE	*Radio and Telecommunications Terminal Equipment*
RED	*Radio Equipment Directive*
RFC	Request for Comments
RRS	Reconfigurable Radio Systems
SAREF	Smart Appliances REFerence
TR	Technical Recommendations
TS	Technical Specifications

4. Executive Abstract

As has been noted in previous versions of the present document conformance with the UNCAP certification suite does not give any indication of conformance with legal requirements for placing a product or service on the market. Instead, the certificate has been envisaged to offer a means to ensure that the UNCAP eco-system can 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 although the role of standards is well addressed in the project as a whole and reported in some detail in both WP6 and in other deliverables in WP5, including the year 3 report on contributions to standardisation, D5.6.

Very simply it is expected that any product seeking UNCAP certification has already been proven to be allowed on the market in the specific country in which it is to be deployed. Thus, as stated in section 5 and in detail in section 7 of the present report a number of regulatory obligations have to be met prior to invoking the steps described in section 8 to achieve UNCAP conformance.

This is the second of two deliverables, the first deliverable was published as a draft in 2016 and is available from download from www.uncap.eu/downloads and the present document is the final version.

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 this report. The UNCAP certification suite has been developed as a part of the UNCAP website (http://www.uncap.eu) that provides guidelines, to help hardware or sensor manufacturers test compliancy of their solutions to the standards supported by UNCAP, and indirectly to 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) described in section 7, and those standards for data modelling and interoperability required by the UNCAP model and which are used as guidelines for the implementation of all of UNCAP's developers and for anyone wishing to attach their product to UNCAP through the use of the certification suite described in section 8.

The purpose of this report is to assist UNCAP partners and associated stakeholders in meeting both their market obligations and to give assurance that products will work together under the UNCAP framework.

5. Table of Contents

6. Market access conformance

6.1. Electrical safety standards (low voltage directive)

The low voltage directive (EU 2006/95/EC) has been superseded by the updated directive 2014/35/EU and each variant is intended to ensure that electrical equipment within certain voltage limits provides a high level of protection for European citizens, and benefits fully from the Single Market. The nature of electrical equipment under the LVD includes those consumer and professional products that constitute the UNCAP physical offering i.e. the UNCAP box, the UNCAP medical and sensing equipment.

It should be noted that UNCAP is not strictly consumer equipment but neither is it strictly professional equipment. This is important as for consumer equipment operating at lower voltages, i.e. consumer goods with a voltage below 50 V AC, or 75 V DC, are dealt with by the General Product Safety Directive (GPSD) 2001/95/EC, which aims to ensure that only safe consumer products are sold in the EU.

No partner in the UNCAP project has been active in the standards relating to this domain of market access. However, the relevant standards that may need to be complied with and which have been notified as harmonised standards in the official journal can be found here:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en

6.2. Radio equipment standards (Radio Equipment Directive)

6.2.1. Overview of RED

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.

Within the UNCAP project partner **C3L** has been active in the ETSI response to the requirements of RED in working to ensure that the harmonised standards originally developed for the R&TTE directive for those wireless technologies used in UNCAP product have been updated under the RED. This has been achieved such that UNCAP product can be placed on the market under the provisions of RED. In addition, UNCAP partner C3L has been active in addressing some of the issues under Article 3.3 of RED which addresses mutable radio devices (e.g. software modifiable radio) to allow for verification of the Declaration of Conformity over the life of the equipment. It is anticipated that such facilities will be essential over the lifetime of UNCAP and UNCAP-like equipment. The relevant specifications which UNCAP Partner C3L has contributed to are the following (see also UNCAP Deliverable D5.6): ETSI TR 103 502 "Reconfigurable Radio Systems (RRS); Applicability of RRS with existing Radio Access

Technologies and core networks; Security aspects"; TS 103 436 "Reconfigurable Radio Systems (RRS); Security requirements for reconfigurable radios"; TR 103 087 "Reconfigurable Radio Systems (RRS); Security related use cases and threats".

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 that is being replaced by RED. The RED applies to equipment that is placed on the market (this contrasts with the R&TTE, which also applied to "relevant components" of radio equipment).

This is important - this means that equipment connecting by Bluetooth or Wi-Fi (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.

6.3. 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.

6.3.1. 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.

6.3.2. 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.

6.3.3. 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.

7. UNCAP internal development standards

7.1. Data transfer representation standard

Data transfers internal to UNCAP are described using JavaScript Object Notation (JSON) and transferred as JSON objects over HTTP or equivalent transfer protocols.

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, developed under responsibility of UNCAP partner FIDA.

There is no formal conformance test suite for JSON.

7.2. User interface style guidelines

7.2.1. Administration interfaces

There are no formal conformance requirements for UNCAP although the guidelines given below apply.

7.2.2. 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.

7.3. 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.

Annex 1. Web FAQ and overview of certification suite

I.i What is UNCAP certification suite?

UNCAP certification suite is a part of the UNCAP products. This is a set of software modules, with relative guidelines, to help you – hardware or sensor manufacturers – develop compliant solutions to the standards supported by UNCAP.

What can I integrate in the UNCAP environment?

Whether you develop a device or a software that is designed to help aging people live independently while maintaining and improving their lifestyle it can interact with the UNCAP environment. The following, presents you ways you can create a product compliant with the UNCAP standards.

I.ii What type of devices are connectable to the UNCAP box or UNCAP cloud?

There is already a list of devices that are connecting to the UNCAP box and cloud that are gathering data and monitoring elder persons:

- Blood Pressure and Heart Rate Monitor.
- Oximeter.
- Scale.
- Glucometer.

These devices, can connect to the UNCAP box that runs on an Android 4.4.4 (or later), or can connect directly to the UNCAP cloud (through the RaptorBox aggregator) to provide the data directly to the server.

You can connect a new type of device, if you develop the driver for it. The data for the device can then already be displayed, if it's in one of the standard, already supported formats. If this is a new type of data, a server-side visualization plugin will also have to be developed.

I.iii How do I provide data from my device to the UNCAP box?

You can connect one of your devices to the UNCAP master app by simply creating a driver for Android, and providing the correct data structure. Here is how your driver and the UNCAP box work:

- UNCAP Driver description and example.
- You can also download a sample of the drivers.

I.iv What is the data structure that must be provided?

Considering that we want to provide a standard we are using standards. So, we use free, open-source code that makes it easy for developers to store/process/integrate digital health data: openMhealth standards. Find your type of device and respect that structure as we do.

I.v Once the driver is developed how do you certify it?

Once you have the driver APK that simulates the data forwarded from your device fill in the form below and attach it. In a matter of 2 weeks you will receive a response from us whether everything is ok or you have to fix anything. If it's all good, we will program all the UNCAP systems to search for your driver. You now just have to advertise the fact that it is UNCAP compatible and to instruct your users how to install your driver. UNCAP will do the rest.

I.vi How can I connect my device straight to the UNCAP cloud?

If you have an even smarter device that connects to the internet you can send data directly to the UNCAP cloud through the UNCAP RaptorBox aggregator.

Register device – credentials – for the new device

User management sends tokens -> User id -> formated data

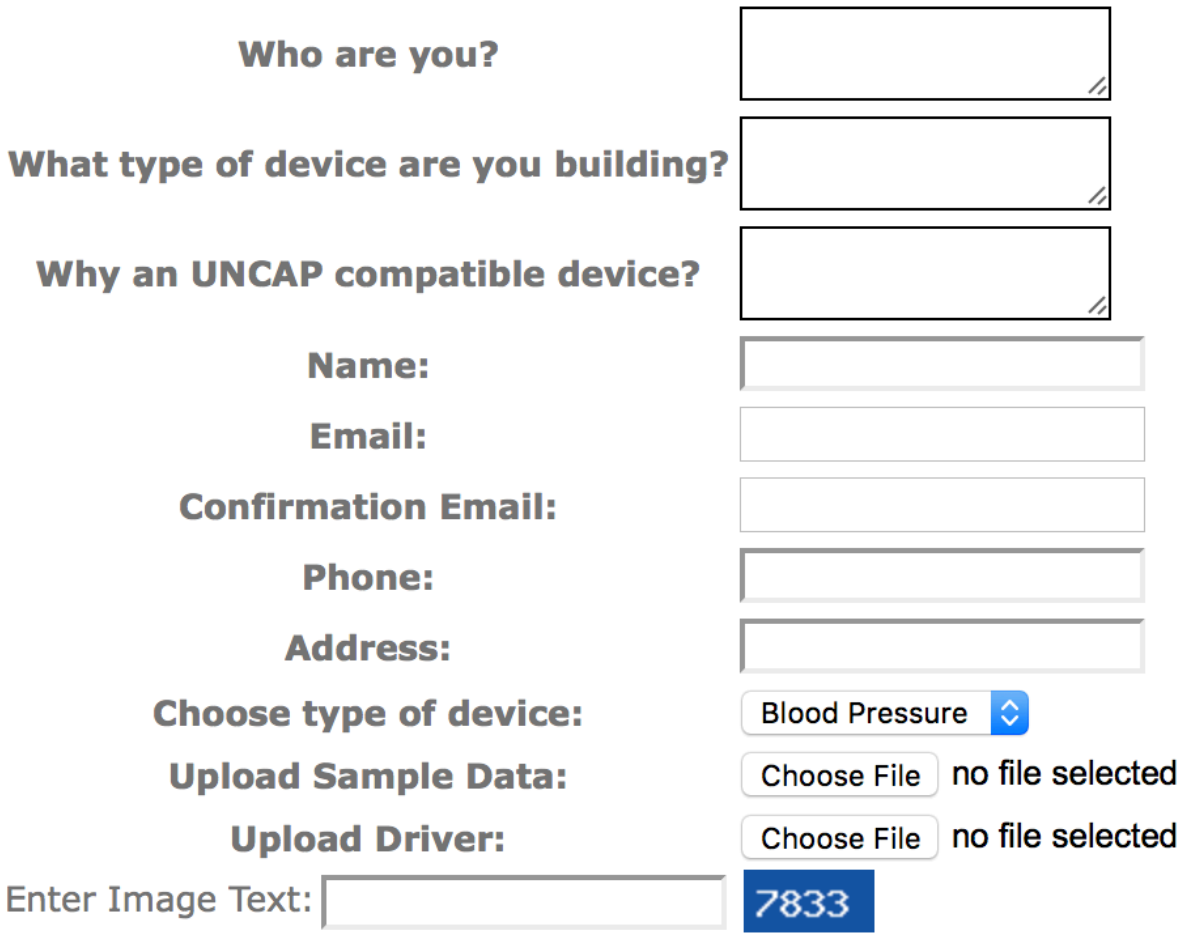
I.vii I don't understand something. What should I do?

If there is something that you need to discuss, please feel free to contact us through the contact form.

I.viii How can I connect my app to the UNCAP system?

If you develop an app – that for example processes data (heart rate and BPM) and can predict the future behaviour of the heart of an elder person – you can get the data from the UNCAP data store and provide the results within the UNCAP interface.

I.ix Certifying device form



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

Internal descriptions of data in the UNCAP model should comply with the draft version of AHA-ML. In due course future versions of UNCAP should follow the eHealth extension to SAREF which offers a semantic model for interoperation of Health and Wellness equipment, particularly those intended for active aging.