SLOVENSKI STANDARD
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Naprave kratkega dosega (SRD) - Medicinske naprave ultra male moči za brezžično kapsulno endoskopijo, ki delujejo v pasu od 430 MHz do 440 MHz - Harmonizirani standard za dostop do radijskega spektra

Short Range Devices (SRD) - Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz - Harmonised Standard for access to radio spectrum

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.1] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.2].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in Table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

National transposition dates	
Date of adoption of this EN:	28 May 2019
Date of latest announcement of this EN (doa):	31 August 2019
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	29 February 2020
Date of withdrawal of any conflicting National Standard (dow):	28 February 2021

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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Introduction

The present document is aiming to cover radio and telecommunications terminal equipment within the scope of the EU's Radio Equipment Directive (RED) [i.2].

The present document specifies conformance requirements for the Ultra Low Power Wireless Medical Capsule Endoscopy SRD application, which includes Capsule Camera (CCam) acting as transmitter and associated Data Recorder (DR) receiver devices, as meant by ETSI TR 103 451 [i.3]. The CCam is designed to wirelessly transmit recorded images from inside patient's gastrointestinal tract to the DR receiver, utilizing a single wideband radio channel occupying the entire designated band 430 MHz to 440 MHz. It is intended that this band will be harmonised for European-wide usage by Ultra Low Power Wireless Medical Endoscopy application through relevant CEPT and EU normative documents in the field of SRD spectrum regulation, such as CEPT/ERC/REC 70-03 [i.4].

CCam transmitters will utilize miniature integral antenna encapsulated within its pill-shaped enclosure. The intended use of the CCam transmitter is inside the human body.

DR receivers will use either integral antenna or dedicated external antenna implemented in the form of skin patch or belt. Such dedicated external antenna would ensure optimal reception of weak radio signals by keeping antenna in direct proximity to the patient's body in the area closest to internal passage of CCam.

These devices would offer opportunity of performing medical endoscopy-type examination of the entire human gastrointestinal tract including the small intestine and colon. Thanks to simple application with minimized risks and side effects, while providing the unique ability to visualize the complete gastrointestinal tract, its use would be highly beneficial and attractive to patients and doctors.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms, symbols and abbreviations used.
- Clause 4 specifies the requirements and limits applicable to CCam transmitter and DR receiver.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.

- Annex A (informative) provides an overview of the relationship between the present document and the essential requirements of the RED [i.2].
- Annex B (normative) describes a human torso simulator test fixture to be used for radiated measurements.
- Annex C (normative) describes the Full Anechoic Room test site configuration for radiated measurements.

1 Scope

The present document specifies technical characteristics and methods of measurements for Ultra Low Power Wireless Medical Capsule Endoscopy application (CCam transmitters and associated DR receivers) operating in the designated frequency band 430 MHz to 440 MHz, as meant by ETSI TR 103 451 [i.3].

A possible return (downlink) RF transmission channel from DR to CCam for command and control signalling, if and when implemented, is outside the scope of the present document.

NOTE: The relationship between the present document and essential requirements of article 3.2 of Directive 2014/53/EU [i.2] is given in Annex A.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at https://docbox.etsi.org/Reference/.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are necessary for the application of the present document.

Not applicable.

2.2 Informative references

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The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.2] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (RED).

[i.3] ETSI TR 103 451: "System Reference document (SRdoc); Short Range Devices (SRD); Technical characteristics for UHF wideband Ultra Low Power Wireless Medical Capsule Endoscopy".

[i.4] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.5] Body Tissue Dielectric Parameters provided by the Federal Communications Commission: "Reference Calculation Tool".

NOTE: Available online at https://www.fcc.gov/general/body-tissue-dielectric-parameters.

[i.6] Bioelectromagnetics (1987): "Simulated biological materials for electromagnetic radiation absorption studies", Hartsgrove G., Kraszewski A. & Surowiec A. 8(1), 29-36.

3 Definition of terms, symbols and abbreviations

3.1 Terms

For the purposes of the present document, the following terms apply:

Capsule Camera (CCam): miniature disposable capsule-shaped optical imaging camera with integrated ultra low RF power SRD transmitter, intended to be swallowed

Data Recorder (DR): device worn by the patient in order to record the stream of images received from CCam and store it

NOTE: At the end of diagnostic procedure the stream of images may be downloaded to doctor's PC for examination.

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

integral antenna: permanent built-in antenna, designed as an indispensable part of the equipment

unwanted emissions in the spurious domain: components at any frequency, generated and radiated by active DR receiver or CCam transmitter outside the defined operating frequency band of 430 MHz to 440 MHz

3.2 Symbols

For the purposes of the present document, the following symbols apply:

dB	decibel
dBm	absolute power level referred to one milliwatt
f	frequency

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

CCam	Capsule Camera
CEPT	European Conference of Postal and Telecommunications administrations
DR	Data Recorder
EC	European Commission
EFTA	European Free Trade Association
e.r.p.	effective radiated power
EU	European Union
EUT	Equipment Under Test
FAR	Fully Anechoic Room
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
TX	Transmitter
VSWR	Voltage Standing Wave Ratio

4 Technical requirements specifications

4.1 Environmental profile

Tests defined in the present document shall be carried out at representative points within the boundary limits of the declared operational environmental profile.

Where technical performance varies subject to environmental conditions, tests shall be carried out under a sufficient variety of environmental conditions (within the boundary limits of the declared operational environmental profile) to give confidence of compliance for the affected technical requirements.

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Effective radiated power

4.2.1.1.1 Definition

The e.r.p. is the total power of CCam TX wanted emissions measured outside test patient's (phantom) body within the designated band 430 MHz to 440 MHz, in the direction of the maximum radiated power under specified conditions of measurements.

4.2.1.1.2 Limit

The e.r.p. of CCam TX shall not exceed -40 dBm/10 MHz total power, -50 dBm/100 kHz e.r.p. density within the designated 430 MHz to 440 MHz band.

4.2.1.1.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.1.1 of the present document.

4.2.1.2 Transmitter emissions mask

4.2.1.2.1 Definition

The transmitter emissions mask envelope shall contain all constituent wanted and unwanted (including the unwanted emissions in the spurious domain) RF emissions of CCam TX as measured outside test patient's (phantom) body in the direction of maximum radiated power under specified conditions of measurements.

4.2.1.2.2 Limits

The transmitter emissions mask limits shall be as given in Figure 1.