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RO-IR 12

TECHNICAL REGULATION

for the radio interface

concerning active medical implants

1. Basic considerations

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 was implemented in national legislation by Government Decision No. 740/2016 on making available on the market of radio equipment.

This technical regulation contains the requirements for the use of licence exempt of radio part in the active medical implants in the specified frequency bands and considers especially compliance with the provisions of Article 3 Paragraph 2 and Articles 6, 7 and 8 of Directive 2014/53/EU.

Nothing in this technical regulation shall preclude the need for equipment placed on the market in Romania to comply with Directive 2014/53/EU.

The obligations arising from Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services have been met (OJ L 241, 17.9.2015, p. 1–15).

All Romanian technical regulations for the radio interfaces notified under Directive 2015/1535 will be published and will be made available on National Authority for Management and Regulation in Communications of Romania (ANCOM) web-site at: http://www.ancom.org.ro/reglementari-interfete_2723

2. Radio Interface Specifications

Active medical implants

Frequency band	**Annex**
9 – 315 kHz	RO-IR 12–01
30 – 37.5 MHz	RO-IR 12–04
401 – 402 MHz	RO-IR 12–05
402 – 405 MHz	RO-IR 12–06
405 – 406 MHz	RO-IR 12–07
2 483.5 – 2 500 MHz	RO-IR 12–08

For the purpose of this technical regulation, *Short Range Device (SRD)* means radio transmitters which provide either unidirectional or bidirectional communication and which transmit over a short distance at low power.

The *active medical implant device* category covers the radio part of active implantable medical devices that are intended to be totally or partially introduced, surgically or medically, into the human body or that of an animal, and where applicable their peripherals.

Active implantable medical devices are defined in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

For the purpose of this technical regulation, the *cycle of use* is defined as the ratio expressed as a percentage, between Σ(Ton)/(Tobs), where Ton is the operating time of a single radio transmitter and Tobs is the observation period. Ton is measured in a frequency observation band (Fobs). Unless otherwise specified in this technical regulation, Tobs represents an one hour uninterrupted period and Fobs is the applicable frequency band of this technical regulation.

For the purpose of this technical regulation *non-interference and non-protected basis* means the interdiction that no harmful interference may be caused to any radio communications service and that no claim may be made for protection of these devices against harmful interference originating from radio communications services.

The use of radio spectrum by short-range devices is allowed on a non-interference and non-protected basis provided that such devices meet the conditions set out in the Annexes.

3. Document history:

Edition	Changes
Edition 1/2014	Notification number according to Directive 98/34/EC: 2014/607/RO.
Edition 2/2018 (06.08.2018)	Update according to implementing Decision (EU) 2017/1483 amending Decision 2006/771/EC on harmonizing the radio spectrum for the use of short range devices and repealing Decision 2006/804/EC: - RO-IR 12-02 and RO-IR 12-03 were repealed; - Update specifications for the radio interface. Update of the legal framework according to Point 1 – „Basic considerations". Formal changes according to TCAM-RSC model of November 2017.

	Nr	Parameter	Description	Comments
Normative part	**1**	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available to active implantable medical devices.*
	3	**Frequency band**	9 – 315 kHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	-	
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	30 dBµA/m at 10 meters	
	8	**Channel occupation and access rules**	Duty cycle limit: 10%	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	**12**	**Planned changes**	-	
	13	**Reference**	EN 302 195; *Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC;* ERC/REC 70-03	
	14	**Notification number**	-	
	15	**Remarks**	-	

	Nr	Parameter	Description	Comments
Normative part	**1**	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available to ultra-low power medical membrane implants for blood pressure measurements within the definition of active implantable medical devices in Directive 90/385/EEC.*
	3	**Frequency band**	30 – 37.5 MHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	-	
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	1 mW effective radiated power (e.r.p.)	
	8	**Channel occupation and access rules**	Duty cycle limit: 10%	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	**12**	**Planned changes**	-	
	13	**Reference**	EN 302 510; Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC; ERC/REC 70-03	
	14	**Notification number**	-	
	15	**Remarks**	-	

	Nr	Parameter	Description	Comments
Normative part	**1**	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information.*
	3	**Frequency band**	401 – 402 MHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	25 kHz Individual transmitters may combine adjacent channels for increased bandwidth up to 100 kHz.	
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	25 µW e.r.p.	
	8	**Channel occupation and access rules**	Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 2014/53/EU shall be used. Alternatively, a duty cycle limit of 0.1 % may also be used.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	**12**	**Planned changes**	-	
	13	**Reference**	EN 302 537; Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC; ERC/DEC/(01)17	
	14	**Notification number**	-	
	15	**Remarks**	-	

F1- RTIR Edition:1; Revision:1

	Nr	Parameter	Description	Comments
Normative part	1	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available to active implantable medical devices.*
	3	**Frequency band**	402 – 405 MHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	25 kHz Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz.	
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	25 µW e.r.p.	
	8	**Channel occupation and access rules**	Other techniques to access spectrum or mitigate interference, including bandwidths greater than 300 kHz can be used provided they result at least in an equivalent performance to the techniques described in harmonised standards adopted under Directive 2014/53/EU, to ensure a compatible operation with the other users and in particular with meteorological radiosondes.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	12	**Planned changes**	-	
	13	**Reference**	EN 301 839; Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC; ERC/DEC/(01)17	
	14	**Notification number**	-	
	15	**Remarks**	-	

	Nr	Parameter	Description	Comments
Normative part	1	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information.*
	3	**Frequency band**	405 – 406 MHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	25 kHz Individual transmitters may combine adjacent channels for increased bandwidth up to 100 kHz.	
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	25 µW e.r.p	
	8	**Channel occupation and access rules**	Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 2014/53/EU shall be used. Alternatively a duty cycle limit of 0.1 % may also be used.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	12	**Planned changes**	-	
	13	**Reference**	EN 302 537; Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC; ERC/DEC/(01)17	
	14	**Notification number**	-	
	15	**Remarks**	-	

	Nr	Parameter	Description	Comments
Normative part	**1**	**Radiocommunication Service**	Mobile	
	2	**Application**	Short Range Devices / Active medical implants	*This set of usage conditions is only available to active implantable medical devices. Peripheral master units are for indoor use only.*
	3	**Frequency band**	2 483.5 – 2 500 MHz	*Harmonised radio spectrum for use by short range devices (Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC)*
	4	**Channeling (channel distribution)**	1 MHz	*The entire frequency band can also be used as a single channel for high speed data transmission.*
	5	**Modulation/Occupied bandwidth**	-	
	6	**Direction/Separation**	-	
	7	**Transmit power / Power density**	10 mW equivalent isotropic radiated power (e.i.r.p.)	
	8	**Channel occupation and access rules**	Duty cycle limit: 10% Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 2014/53/EU shall be used.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)**	-	
	11	**Assumptions on spectrum planning**	-	
Informative Part	**12**	**Planned changes**	-	
	13	**Reference**	EN 301 559; Decision 2017/1483/EU amending Decision 2006/771/EC on the harmonization of radio frequencies spectrum for the use of short range devices and repealing Decision 2006/804/EC; ERC/REC 70-03	
	14	**Notification number**	-	
	15	**Remarks**	-	