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RO-IR 12

TECHNICAL REGULATION

for the radio interface

concerning active medical implants

98/34/EC Notification number: 2014/607/RO

1. Basic considerations

The Radio Equipment and Telecommunications Terminal Equipment Directive 1999/5/EC (R&TTE Directive) was implemented in Romania (RO) by Government Decision No. 130/2015.

This technical regulation contains the necessary equipment parameters for the use of licence exempt active medical implants in the specified frequency bands and considers especially compliance with Articles 3.2, 4.1, 6 and 7.2 of Directive 1999/5/EC.

Nothing in this technical regulation shall preclude the need for equipment placed on the market in Romania to comply with Directive 1999/5/EC.

The obligations arising from Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 204 p. 37), as amended by Directive 98/48/EC of the European Parliament and of the Council of 20 July 1998 (OJ L 217 p. 18), have been met.

All Romanian technical regulations notified under Directive 1998/34/EC will be published and will be made available free of charge from the ANCOM web-site at:
http://www.ancom.org.ro/en/interface-regulations-_2723

2. Radio Interface Specifications

Active medical implants

Frequency band	**Annex**
9 – 315 kHz	RO-IR 12–01
315 – 600 kHz	RO-IR 12–02
12 500 – 20 000 kHz	RO-IR 12–03
30 – 37.5 MHz	RO-IR 12–04
401 – 402 MHz 402 – 405 MHz	RO-IR 12–05 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).

Animal implantable devices are transmitting devices which are placed inside the body of an animal for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment.

For the purpose of this technical regulation, *non-interference and non-protected basis* means 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 device is allowed on a non-interference and non-protected basis provided that such device meets the conditions set out in the Annexes.

	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 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	-	
	5	**Modulation / Occupied bandwidth**	-	
	6	**Direction / Separation**	-	
	7	**Transmit power / Power density**	30 dBµA/m at 10 metres	
	8	**Channel access and occupation rules**	Duty cycle limit: 10 %	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**		
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 302 195; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/REC 70-03	
	14	**Notification number**	2014/607/RO	
	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 animal implantable devices	
	3	**Frequency band**	315 – 600 kHz	*Harmonised radio spectrum for use by short-range devices (Decision 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	-	
	5	**Modulation / Occupied bandwidth**	-	
	6	**Direction / Separation**	-	
	7	**Transmit power / Power density**	– 5 dBµA/m at 10 metres	
	8	**Channel access and occupation rules**	Duty cycle limit: 10 %	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 302 536; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/REC 70-03	
	14	**Notification number**	2014/607/RO	
	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 indoor use by animal implantable devices	
	3	**Frequency band**	12 500 – 20 000 kHz	*Harmonised radio spectrum for use by short-range devices (Decision 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	-	
	5	**Modulation / Occupied bandwidth**	-	
	6	**Direction / Separation**	-	
	7	**Transmit power / Power density**	– 7 dBµA/m at 10 metres in a bandwidth of 10 kHz	
	8	**Channel access and occupation rules**	Duty cycle limit: 10 %	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 300 330; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/REC 70-03	
	14	**Notification number**	2014/607/RO	
	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 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	-	
	5	**Modulation / Occupied bandwidth**	-	
	6	**Direction / Separation**	-	
	7	**Transmit power / Power density**	1 mW effective radiated power (e.r.p.)	
	8	**Channel access and occupation rules**	Duty cycle limit: 10 %	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 302 510; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/REC 70-03	
	14	**Notification number**	2014/607/RO	
	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 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	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 access and occupation rules**	Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 1999/5/EC must be used. Alternatively a duty cycle limit of 0,1 % may also be used.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 302 537; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/DEC/(01)17	
	14	**Notification number**	2014/607/RO	
	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	
	3	**Frequency band**	402 – 405 MHz	*Harmonised radio spectrum for use by short-range devices (Decision 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	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 access and occupation 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 1999/5/EC to ensure compatible operation with the other users and in particular with meteorological radiosondes.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 301 839; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/DEC/(01)17	
	14	**Notification number**	2014/607/RO	
	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 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	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 access and occupation rules**	Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 1999/5/EC must be used. Alternatively a duty cycle limit of 0,1 % may also be used.	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 302 537; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/DEC/(01)17	
	14	**Notification number**	2014/607/RO	
	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 2013/752/EU amending Decision 2006/771/EC)*
	4	**Channelling**	1 MHz The whole frequency band may also be used dynamically as a single channel for high-speed data transmissions.	
	5	**Modulation / Occupied bandwidth**	-	
	6	**Direction / Separation**	-	
	7	**Transmit power / Power density**	10 mW equivalent isotropic radiated power (e.i.r.p.)	
	8	**Channel access and occupation rules**	Techniques to access spectrum and mitigate interference that provide at least equivalent performance to the techniques described in harmonised standards adopted under Directive 1999/5/EC must be used. Duty cycle limit of 10 %	
	9	**Authorisation regime**	Licence exemption	
	10	**Additional essential requirements**	-	
	11	**Frequency planning assumptions**	-	
Informative part	12	**Planned changes**	-	
	13	**Reference**	EN 301 559; Decision 2013/752/EU amending Decision 2006/771/EC; ERC/REC 70-03	
	14	**Notification number**	2014/607/RO	
	15	**Remarks**	-	