

**RO-IR SRD-10**

**TECHNICAL REGULATION**

**for the radio interface**

**concerning active implantable medical devices**

**(previous coding RO-IR 12)**

## 1. Basic Considerations

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 was implemented in national legislation by Government Decision No 740/2016 on making available on the market of radio equipment, with subsequent amendments and completions.

This technical regulation contains the requirements for license-exempt use of radio spectrum by radio component from active implantable medical devices in the specified radio frequency bands and considers compliance, especially, with the provisions of Article 3 Paragraph 2 and Articles 6-8 of Directive 2014/53/EU.

Nothing in this technical regulation shall preclude the obligation for radio equipment placed on the market or made available 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 are met in this regulation (OJ L 241, 17.9.2015, p. 1-15).

All the Romanian technical regulations for the radio interfaces notified under Directive (EU) 2015/1535 shall be published and made available on National Authority for Management and Regulation in Communications (ANCOM) website at: [https://www.ancom.ro/en/romanian-regulation\\_2719](https://www.ancom.ro/en/romanian-regulation_2719).

## 2. Radio Interface Specifications

### Active implantable medical devices

Frequency band	Annex
9 – 315 kHz	RO-IR SRD-10-01
30 – 37.5 MHz	RO-IR SRD-10-02
401 – 402 MHz	RO-IR SRD-10-03
402 – 405 MHz	RO-IR SRD-10-04
405 – 406 MHz	RO-IR SRD-10-05
2 483.5 – 2 500 MHz	RO-IR SRD-10-06

For the purpose of this technical regulation, a *proximity radio device (short-range device - SRD)* means a radio device which provides either unidirectional or bidirectional communication and which receives and/or transmits signals over a short distance and at a low power.

The *active implantable medical 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 of an animal, and where applicable, their peripherals.

The 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  $\Sigma(Ton)$  and  $(Tobs)$ , where *Ton* is the operating time of a single radio transmitter device and *Tobs* is the observation period. *Ton* is measured in a frequency observation

band (*Fobs*). Unless otherwise specified in this technical regulation, *Tobs* represents a 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 that no harmful interference may be caused to any radio communications services and that no claim may be made for protection of these devices against harmful interferences originating from radio communications services.

The use of radio spectrum by proximity radio devices (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 below.

### 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 Commission 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: <ul style="list-style-type: none"> <li>• RO-IR 12-02 and RO-IR 12-03 were eliminated;</li> <li>• Update of radio interface specifications.</li> </ul> Update of the legal framework according to Point 1 – „Basic considerations“. Formal changes according to TCAM-RSC model of November 2017.
Edition 3/2020 (23.12.2020)	Update according to Commission Implementing Decision (EU) 2019/1345 amending Decision 2006/771/EC in order to update the harmonised technical conditions for the use of radio spectrum for short-range devices: <ul style="list-style-type: none"> <li>• Implementation/updating of some definitions and terms;</li> <li>• Renumbering of the annexes.</li> </ul> Update according to the list of Class 1 radio equipment subclasses (version of January 2020) published according to Article 1 Paragraph (3) of Commission Decision 2000/299/EC ( <a href="https://ec.europa.eu/docsroom/documents/40361">https://ec.europa.eu/docsroom/documents/40361</a> ).
Edition 4/2022 (11.10.2022)	Update according to Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices: <ul style="list-style-type: none"> <li>• Updating the reference documents (line 13) and definitions Point 2.</li> </ul>

ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-01	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	Radiocommunication Service	Mobile	
	2	Application	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies to active implantable medical devices.</i>
	3	Frequency band	9 – 315 kHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	Channelling (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; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-02	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	Radiocommunication Service	Mobile	
	2	Application	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies to ultra-low power medical implantable membranes used for blood pressure measurements, which are included within the definition of active implantable medical devices.</i>
	3	Frequency band	30 – 37.5 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	Channelling (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; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-03	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	<b>Radiocommunication Service</b>	Mobile	
	2	<b>Application</b>	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies 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-emergency physiological information about the patient.</i>
	3	<b>Frequency band</b>	401 – 402 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	<b>Channelling (channel distribution)</b>	25 kHz Individual transmitters may combine adjacent channels to increase bandwidth up to 100 kHz.	
	5	<b>Modulation/Occupied bandwidth</b>	-	
	6	<b>Direction/Separation</b>	-	
	7	<b>Transmit power / Power density</b>	25 µW e.r.p.	
	8	<b>Channel occupation and access rules</b>	Requirements on techniques to access radio spectrum and mitigate interference apply. Alternatively, a duty cycle limit of 0.1 % may be used.	<i>Techniques to access radio spectrum and mitigate interference are used, ensuring an adequate performance level to meet the essential requirements provided in Directive 2014/53/EU. If the relevant techniques are described in the harmonized standards (or parts thereof) the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, a performance at least equivalent to the performance of these techniques shall be ensured.</i>
	9	<b>Authorisation regime</b>	Licence exemption	
	10	<b>Additional essential requirements (According to Article 3 Paragraph 3 of 2014/53/EU Directive)</b>	-	
	11	<b>Assumptions on spectrum planning</b>	-	
Informative part	12	<b>Planned changes</b>	-	
	13	<b>Reference</b>	EN 302 537; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/DEC/(01)17; ERC/REC 70-03	
	14	<b>Notification number</b>	-	
	15	<b>Remarks</b>	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-04	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	Radiocommunication Service	Mobile	
	2	Application	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies to active implantable medical devices.</i>
	3	Frequency band	402 – 405 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	Channelling (channel distribution)	25 kHz Individual transmitters may combine adjacent channels to increase 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	Techniques to access radio spectrum and mitigate interference may be used, including bandwidths greater than 300 kHz, provided that they ensure a compatible operation with the other users and, in particular, with meteorological radiosondes.	<i>Techniques to access radio spectrum and mitigate interference are used, ensuring an adequate performance level to meet the essential requirements provided in Directive 2014/53/EU. If the relevant techniques are described in the harmonized standards (or parts thereof) the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, a performance at least equivalent to the performance of these techniques shall be ensured.</i>
	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; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/DEC/(01)17; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-05	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	Radiocommunication Service	Mobile	
	2	Application	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies 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-emergency physiological information about the patient.</i>
	3	Frequency band	405 – 406 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	Channelling (channel distribution)	25 kHz Individual transmitters may combine adjacent channels to increase 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	Requirements on techniques to access radio spectrum and mitigate interference apply. Alternatively, a duty cycle limit of 0.1 % may be used.	<i>Techniques to access radio spectrum and mitigate interference are used, ensuring an adequate performance level to meet the essential requirements provided in Directive 2014/53/EU. If the relevant techniques are described in the harmonized standards (or parts thereof) the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, a performance at least equivalent to the performance of these techniques shall be ensured.</i>
	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; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/DEC/(01)17; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-06	Edition 4/2022
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	No	Parameter	Description	Comments
Normative part	1	Radiocommunication Service	Mobile	
	2	Application	Proximity radio device (short-range) / Active implantable medical devices	<i>This set of usage conditions only applies to active implantable medical devices. Peripheral master units are for indoor use only.</i>
	3	Frequency band	2 483.5 – 2 500 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices)</i>
	4	Channelling (channel distribution)	1 MHz	<i>The entire frequency band can also be used, dynamically, as a single channel for high-speed data transmission.</i>
	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	Requirements on techniques to access radio spectrum and mitigate interference apply. In addition, a duty cycle limit of 10% applies.	<i>Techniques to access radio spectrum and mitigate interference are used, ensuring an adequate performance level to meet the essential requirements provided in Directive 2014/53/EU. If the relevant techniques are described in the harmonized standards (or parts thereof) the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, a performance at least equivalent to the performance of these techniques shall be ensured.</i>
	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; Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC as regards the update of harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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