

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 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 shall be made available on National Authority for Management and Regulation in Communications (ANCOM) website at: http://www.ancom.ro/reglementari-interfete_2723.

2. Radio Interface Specifications

Active Implantable Medical Devices

Frequency band	Annex
9 – 315 kHz	RO-IR SRD-10-01
315 – 600 kHz	RO-IR SRD-10-02
12500 – 20000 kHz	RO-IR SRD-10-03
30 – 37.5 MHz	RO-IR SRD-10-04
401 – 402 MHz	RO-IR SRD-10-05
402 – 405 MHz	RO-IR SRD-10-06
405 – 406 MHz	RO-IR SRD-10-07
2483.5 – 2500 MHz	RO-IR SRD-10-08

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 low power.

The *active implantable medical devices* category covers the radio part of active implantable medical devices that are intended to be fully 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 (OJL 189, 20.7.1990, p. 17).

For the purpose of this technical regulation, *duty cycle* means the ratio, expressed as a percentage, of $\Sigma(Ton)/(Tobs)$ where *Ton* is the "on" time of a single transmitter device and *Tobs* is the observation period. *Ton* is measured in an observation frequency band (*Fobs*). Unless otherwise

specified in this technical annex, *Tobs* is a continuous one hour period and *Fobs* is the applicable frequency band in this technical annex.

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

The use of radio spectrum by short-range devices is permitted on a non-interference and non-protected basis provided that such equipment meets the conditions set out in the Annex.

3. Document History:

Edition	Change
Edition 1/2014	Notification number according to Directive 98/34/EC: 2014/607/RO.
Edition 2/2018 (06.08.2018)	<p>Update according to Commission Implementing Decision (EU) 2017/1483 amending Decision 2006/771/EC on harmonization of the radio spectrum for use by short-range devices and repealing Decision 2006/804/EC:</p> <ul style="list-style-type: none"> • RO-IR 12-02 and RO-IR 12-03 have been eliminated; • Update of radio interface specifications. <p>Update of the legal framework according to Point 1 – „Basic considerations”. Formal changes according to TCAM-RSC model of November 2017.</p>
Edition 3/2020 (23.12.2020)	<p>Update according to Commission Implementing Decision (EU) 2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices:</p> <ul style="list-style-type: none"> • Some definitions and terms have been introduced/updated; • Renumbering of the annexes. <p>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 (https://ec.europa.eu/docsroom/documents/40361).</p>
Edition 4/2022 (11.10.2022)	<p>Update according to Commission Implementing Decision (EU) 2022/180 amending Decision 2006/771/EC on the harmonization of radio spectrum for use by short-range devices:</p> <ul style="list-style-type: none"> • Update of reference documents (line 13) and definitions point 2.

Edition 5/2025 (22.12.2025)	<p>Update according to Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union:</p> <ul style="list-style-type: none">• Two new harmonised frequency bands (315 – 600 kHz and 12500 – 20000 kHz) have been introduced exclusively for animals;• Bandwidth change for the 401 – 402 MHz, 402 – 405 MHz and 405 – 406 MHz frequency bands;• Imposition of a duty cycle limit for peripherals in the 2483.5 – 2500 MHz frequency band;• Renumbering of annexes;• Reference documents (line 13).
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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-01	Edition 5/2025
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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	
	3	Frequency band	9 – 315 kHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	4	Channeling (channel distribution)	-	
	5	Modulation/Occupied bandwidth	-	
	6	Direction/Separation	-	
	7	Transmit power / Power density	30 dB μ A/m at 10 meters	
	8	Channel occupation and access rules	Duty cycle: \leq 10%	
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; 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 5/2025
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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 is only available for animal implant devices for indoor use.</i>
	3	Frequency band	315 – 600 kHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	4	Channeling (channel distribution)	-	
	5	Modulation/Occupied bandwidth	-	
	6	Direction/Separation	-	
	7	Transmit power / Power density	- 5 dBµA/m at 10 meters	
	8	Channel occupation and access rules	Duty cycle: ≤ 10%	
	9	Authorization regime	License 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 302 536; Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; 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 5/2025
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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 is only available for indoor use by animal implant devices.</i>
	3	Frequency band	12500 – 20000 kHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	4	Channeling (channel distribution)	-	
	5	Modulation/Occupied bandwidth	-	
	6	Direction/Separation	-	
	7	Transmit power / Power density	- 7 dBμA/m at 10 meters in any bandwidth of 10 kHz	
	8	Channel occupation and access rules	Duty cycle: ≤ 10%	
	9	Authorization regime	License 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 300 330; Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	
	15	Radiocommunication Service	-	

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ROMANIA	Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-04	Edition 5/2025
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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 is only available for ultra-low power medical membrane implants for blood pressure measurements.</i>
	3	Frequency band	30 – 37.5 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	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: ≤ 10%	
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

F1- RTIR Edition:1; Revision:1

ROMANIA		Radio Interface Specification	SRD / Active Implantable Medical Devices	RO-IR SRD-10-05	Edition 5/2025
Normative Part	No.	Parameter	Description	Comments	
	1	Radiocommunication Service	Mobile		
	2	Application	Proximity radio device (short-range) / Active Implantable Medical Devices	<i>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.</i>	
	3	Frequency band	401 – 402 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>	
	4	Channeling (channel distribution)	-		
	5	Modulation/Occupied bandwidth	Bandwidth ≤ 100 kHz		
	6	Direction/Separation	-		
	7	Transmit power / Power density	25 µW e.r.p.		
	8	Channel occupation and access rules	Requirements on techniques to access spectrum and mitigate interference apply. Alternatively, a duty cycle of 0.1 % applies.	<i>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</i>	
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; 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 5/2025
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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	
	3	Frequency band	402 – 405 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	4	Channeling (channel distribution)	-	
	5	Modulation/Occupied bandwidth	Bandwidth \leq 300 kHz	
	6	Direction/Separation	-	
	7	Transmit power / Power density	25 μ W 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 ensure compatible operation with the other users and in particular with meteorological radiosondes.	<i>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</i>
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; 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-10-07	Edition 5/2025
Normative Part	No.	Parameter	Description	Comments	
	1	Radiocommunication Service	Mobile		
	2	Application	Proximity radio device (short-range) / Active Implantable Medical Devices	<i>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.</i>	
	3	Frequency band	405 – 406 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>	
	4	Channeling (channel distribution)	-		
	5	Modulation/Occupied bandwidth	Bandwidth ≤ 100 kHz		
	6	Direction/Separation	-		
	7	Transmit power / Power density	25 μW e.r.p.		
	8	Channel occupation and access rules	Requirements on techniques to access spectrum and mitigate interference apply Alternatively, a duty cycle of 0.1 % applies.	<i>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</i>	
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; 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-10-08	Edition 5/2025
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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>Peripheral master units are for indoor use only.</i>
	3	Frequency band	2483.5 – 2500 MHz	<i>Harmonised radio spectrum for use by short-range devices (Commission Implementing Decision (EU) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union)</i>
	4	Channeling (channel distribution)	-	
	5	Modulation/Occupied bandwidth	Bandwidth \leq 1 MHz	<i>The whole frequency band may also be used dynamically as a single channel to maintain a communications session.</i>
	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 spectrum and mitigate interference apply. Duty cycle for peripherals: \leq 10%.	<i>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</i>
	9	Authorization regime	License 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) 2025/105 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices and repealing Implementing Decision 2014/641/EU on harmonised technical conditions of radio spectrum use by wireless audio programme making and special events equipment in the Union; ERC/REC 70-03	
	14	Notification number	-	
	15	Remarks	-	

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