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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, with subsequent amendments and completions.

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

This technical regulation does not exclude the obligation that the radio equipment placed on the market or made available on the market in Romania shall comply with the 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 by this regulation (OJ L 241, 17.9.2015, pages 1-15).

All 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) web-site at: http://www.ancom.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 12–02 |
| 401 – 402 MHz | RO-IR 12–03 |
| 402 – 405 MHz | RO-IR 12–04 |
| 405 – 406 MHz | RO-IR 12–05 |
| 2 483.5 – 2 500 MHz | RO-IR 12–06 |

For the purpose of this technical regulation, Short-Range Device (SRD) means a radio device, which provides unidirectional or bidirectional communication and which receives and/or transmits signals over a short distance and with low power.

The *active implantable medical devices* 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 (OJL 189, 20.7.1990, page 17).

For the purpose of this technical regulation, the *duty cycle* is defined as the ratio expressed as a percentage, between Σ(Ton) and (Tobs), where Ton is the operating time («on») 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 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* means that it is not allowed to cause any harmful interference to radio communications service and that it shall not be claimed the 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 below.

**3. Document history:**

| Edition | Changes |
|---|---|
| Edition 1/2014 | Notification number according to Directive 98/34/EC: 2014/607/RO. |
| Edition 2/2018<br>(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:<br>• RO-IR 12-02 and RO-IR 12-03 were abandoned;<br>• Update of the specifications for the radio interface.<br>Update of the legal framework according to Point 1 – „Basic considerations".<br>Formal changes according to TCAM-RSC pattern of November 2017. |
| Edition 3/2020<br>(23.12.2020) | 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:<br>• Introduction / updating of some definitions and terms;<br>• Renumbering of annexes.<br>Update according to the list of Class 1 radio equipment subclasses (January 2020 version) published according to Article 1 Paragraph 3 of Commission Decision 2000/299/EC (https://ec.europa.eu/docsroom/documents/40361). |

| | Nr | Parameter | Description | Comments |
|---|---|---|---|---|
| Normative Part | 1 | **Radiocommunication Service** | Mobile | |
| | 2 | **Application** | Short-Range Devices / Active medical implants | *This set of usage conditions applies only to active implantable medical devices.* |
| | 3 | **Frequency band** | 9 – 315 kHz | *Harmonised radio spectrum for use by short-range devices (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)* |
| | 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** | Operating cycle limit : 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)2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; 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 applies only to ultra-low power implantable medical membranes for blood pressure measurements included in the definition of active implantable medical devices.* |
| | 3 | **Frequency band** | 30 – 37.5 MHz | *Harmonised radio spectrum for use by short-range devices (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)* |
| | 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** | Operating cycle limit : 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) 2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/REC 70-03 | |
| | 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 applies only for systems specially 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 and 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 (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)* |
| | 4 | **Channeling (channel distribution)** | 25 kHz<br>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 spectrum and mitigate interference shall apply.<br>An operating cycle limit of 0.1 % may also be used. | *Techniques to access spectrum and mitigate interference that provide an appropriate performance level to meet the essential requirements provided in Directive 2014/53/EU shall apply. 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 performance of these techniques shall be ensured.* |
| | 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) 2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; 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 applies only to active implantable medical devices.* |
| | 3 | **Frequency band** | 402 – 405 MHz | *Harmonised radio spectrum for use by short-range devices (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)* |
| | 4 | **Channeling (channel distribution)** | 25 kHz<br>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** | Other techniques to access spectrum and mitigate interference, including bandwidths greater than 300 kHz, provided to ensure a compatible operation with the other users and in particular with meteorological radiosondes may be used. | *Techniques to access spectrum and mitigate interference that provide an appropriate performance level to meet the essential requirements provided in Directive 2014/53/EU shall apply. 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 performance of these techniques shall be ensured.* |
| | 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) 2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; 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 applies only for systems specially 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 (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)* |
| | 4 | **Channeling (channel distribution)** | 25 kHz<br>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 spectrum and mitigate interference shall apply.<br><br>An operating cycle limit of 0.1 % may also, be used. | *Techniques to access spectrum and mitigate interference that provide an appropriate performance level to meet the essential requirements provided in Directive 2014/53/EU shall apply. 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 performance of these techniques shall be ensured.* |
| | 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) 2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; 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 applies only to active implantable medical devices. Peripheral master units shall be used indoor only.* |
| | 3 | **Frequency band** | 2 483.5 – 2 500 MHz | *Harmonised radio spectrum for use by short-range devices (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)* |
| | 4 | **Channeling (channel distribution)** | 1 MHz | *The entire frequency band may also be used, dynamically, 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** | Requirements on techniques to access spectrum and mitigate interference shall apply.<br>Operating cycle limit: 10% | *Techniques to access spectrum and mitigate interference that provide an appropriate performance level to meet the essential requirements provided in Directive 2014/53/EU shall apply. 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 performance of these techniques shall be ensured.* |
| | 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)2019/1345 amending Decision 2006/771/EC updating harmonised technical conditions in the area of radio spectrum use for short-range devices; ERC/REC 70-03 | |
| | 14 | **Notification number** | - | |
| | 15 | **Remarks** | - | |

F1- RTIR Edition:1; Revision:1