



## Summary of Safety and Clinical Performance ROOTT Dental Implant System

**Device category:** Two-piece implants (ROOTT R)

### Preface

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the ROOTT R dental implants.

The SSCP is not intended to replace the Instructions for Use (IFU), which remain the primary source of information for the safe and correct use of the device. It is also not intended to provide diagnostic or therapeutic advice to intended users or patients. The following information is intended for users / healthcare professionals.

### Manufacturer details:

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### 1. Device identification and general information

Device Name / Trade Name:	ROOTT
Device Group / Family:	Endosseous dental implants (ROOTT R)
Basic UDI-DI:	76300538ROOTTRTX
Intended Use:	<p><b>Dental implants</b> are intended to replace missing or corrupted teeth,</p> <ul style="list-style-type: none"><li>a) that are not possible to be repaired, replaced or compensated by other means;</li><li>b) where other solutions have an undesired impact on sound teeth, or</li><li>c) where implants are desired for obtaining an optimal cosmetic result.</li></ul> <p>ROOTT Dental Implants are intended for surgical placement in the maxilla or mandible to provide stable anchorage for prosthetic superstructures for tooth restoration. The implants may be used as terminal or intermediary abutments for fixed or removable bridgework and for the retention of overdentures.</p>
Indications	The medical indications for the use of ROOTT Dental implants and related to their superstructures are:

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	<ul style="list-style-type: none"> <li>- loss of teeth / missing teeth,</li> <li>- replacement of damaged or ill teeth</li> </ul>
Intended User:	Qualified dental professionals only
Target Population:	<p>The target population includes patients who meet all of the following general characteristics:</p> <ul style="list-style-type: none"> <li>- Adults with completed craniofacial growth, typically <math>\geq 18</math> years.</li> <li>- General health status suitable for surgical and restorative treatment</li> <li>- Patients with adequate bone quality and quantity (or who can be clinically managed to achieve this) to support implant placement and predictable osseointegration, as assessed by the implantologist.</li> </ul> <p>No convincing evidence indicates that age or gender alone affects outcomes of prosthetic rehabilitation in the short or long term. Therefore, age and gender are not considered limiting factors within the adult, skeletally mature population; however, individual clinical assessment remains necessary.</p> <p><b>Excluded / not-target population</b></p> <ul style="list-style-type: none"> <li>- Patients with ongoing craniofacial growth, typically <math>&lt; 18</math> years, or any patient where skeletal growth is not complete, due to the risk of implant position changes relative to the developing dentition and jaw skeleton.</li> <li>- Patients not medically suitable for surgical/restorative procedures, as determined by clinician judgement (with contraindications to oral surgery).</li> <li>- Patients with insufficient bone quality/quantity for implant therapy where clinical management cannot reasonably establish adequate conditions (per clinician assessment).</li> </ul>
Anatomical Site / Application Area:	The upper and / or lower jaw
Medical Indications:	<p>The medical indications for the use of ROOTT Dental implants and related to their superstructures are:</p> <ul style="list-style-type: none"> <li>- loss of teeth / missing teeth,</li> <li>- replacement of damaged or ill teeth</li> </ul>
Mode of Action / Mechanism:	Dental implants are surgically placed endosseous devices that achieve primary mechanical stability in the jawbone at insertion. During healing, the implant surface supports osseointegration - the formation of a direct, stable interface between living bone and the implant - resulting in long-term anchorage. Once integrated, the implant functions as an artificial tooth root, transferring chewing forces through the abutment and prosthetic restoration into the surrounding bone, thereby enabling functional and aesthetic prosthetic rehabilitation
Clinical Condition Addressed:	The devices are intended for use in dental clinics, surgical rooms, or hospitals equipped for dental implant procedures under aseptic conditions
Contraindications	<b>Absolute contraindications are:</b>

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	<p>myocardial infarction (within six months of an attack), cerebral infarction and cerebral apoplexy (in cases where the condition of the disease is serious and the patient is concurrently taking anticoagulants), severe immunodeficiency, patients who are undergoing strong chemotherapy, severe neuropsychiatric disease, mental disability, patients who are concurrently taking bisphosphonates, youths under the age of 18, allergies or hypersensitivities to chemical ingredients of material used (titanium alloy, TiN).</p> <p><b>Relative contraindications are:</b> diabetes (particularly insulin-dependent), angina pectoris (angina), seropositivity (absolute contraindication for clinical AIDS), significant consumption of tobacco, certain mental diseases, radiotherapy to the neck or face (depending on the zone, the quantity of radiation, localization of the cancerous lesion etc.), certain auto-immunes diseases, drug, narcotic, alcohol dependency, pregnancy, certain diseases of the mucous membranes of the mouth, bruxism, periodontal diseases (loosening of the teeth): it is necessary to clean up the gums and stabilise the disease first, an unbalanced relationship between the upper and lower teeth, poor oral hygiene, an insufficient quantity of bone, infections in the neighbouring teeth (pockets, cysts, granulomas), major sinusitis.</p> <p><b>Abutments / healing abutments</b> are only used if dental implants are placed, so all contraindications that prohibit the use of dental implants prohibit the use of the abutments as well. The contraindications of the abutments are always connected to that of the dental implants.</p>
Limitations	<p>The ROOTT R dental implant with a 3.0 mm diameter is intended for placement in the central incisor region for single-tooth restorations. In addition, the 3.0 mm diameter ROOTT R implant may be used as part of a multiple-unit restoration in the central incisor region, provided that the overall treatment plan includes a minimum of six implants.</p> <p>For single-tooth restorations, the ROOTT R implant (3.0 mm) shall be used with caution and only where adequate primary stability is achieved at placement (recommended insertion torque <math>\geq 35</math> Ncm)</p>
Lifecycle Stage:	Legacy devices
EMDN code	P01020101, DENTAL IMPLANTS
First certificate (CE) issue date	2012

### Device classification:

**Long Term duration:** Normally intended for continuous use for more than 30 days.

**Surgically invasive device:** An invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation.

**Implantable.**

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According to the Annex VIII of Regulation (EU) 2017/745 on medical devices **Dental Implants and Related Dental Superstructures** are classified as **class IIb** medical devices in accordance with: **Rule 8, second paragraph**: All implantable devices and long-term surgically invasive devices are classified as **class IIb** unless they [...].

## 2. Device description



The ROOTT Dental Implant System comprises endosseous dental implants and associated components, including abutments, healing abutments, cover and fixation screws, other prosthetic components, and dedicated surgical instruments.

ROOTT R Dental Implants are intended for single-tooth and multiple-unit restorations with immediate or delayed loading in the maxilla and mandible, across a range of bone qualities, where clinically appropriate. Implants may be placed using flap or flapless techniques, at crestal or subcrestal level, depending on the clinical situation. Placement may also be performed immediately following tooth extraction, provided that sufficient bone volume and primary stability can be achieved.

ROOTT R Dental Implants are manufactured from titanium alloy (Ti-6Al-4V ELI) and supplied sterile.

ROOTT R implants are available in different size configurations (diameter and length)	R3010, R3012, R3014, R3016, R3506, R3508, R3510, R3512, R3514, R3516, R3518, R3520, R3806, R3808, R3810, R3812, R3814, R3816, R3818, R3820, R4206, R4208, R4210, R4212, R4214, R4216, R4806, R4808, R4810, R4812, R4814, R4816, R5506, R5508, R5510, R5512, R5514, R5516, R6506, R6508, R6510, R6512, R6514, R7506, R7508, R7510, R7512, R7514, R8506, R8508, R8510, R8512, R8514
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### 3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

ROOTT R Dental Implants do not incorporate novel features compared with comparable state-of-the-art products currently available on the market. The design of the devices does not include any fundamental or critical innovations or modifications and is consistent with the current level of technique (state of the art). No clinically relevant changes have been made to the devices.

### 3.3. List of any accessories covered by this plan:

Implants ROOTT R: cover screw.

### 3.4. Description of any other devices and products which are intended to be used in combination with the device

The ROOTT Dental Implant System also includes additional devices intended to be used in combination with the implants that are not covered by this report, including:

- Healing abutments and prosthetic abutments;
- Related superstructures (Class I devices), such as transfers, implant analogs, scan posts, and burnout components;
- Associated instruments, including implant drills and handpiece instruments, reusable surgical instruments, and auxiliary tools.

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### 4. Risks and warnings

#### 4.1. Residual risks and undesirable side-effects

##### Residual risks

A 100% implant success rate cannot be guaranteed. Failure to follow the indicated limitations, instructions, and procedural steps may result in treatment failure. Improper use of the products may lead to suboptimal clinical outcomes and increased risks.

Failure to correctly determine implant length relative to radiographic measurements may result in permanent injury to nerves or other vital anatomical structures. Over-drilling in the mandible may cause permanent numbness of the lower lip and chin and/or haemorrhage in the floor of the mouth.

Reuse of single-use devices increases the risk of contamination and cross-contamination and may result in implant failure.

Implant treatment may lead to bone loss and biological and/or mechanical complications, including fatigue fracture of implants. Close cooperation between the surgeon, restorative dentist, and dental laboratory technician is essential for successful implant therapy.

Mechanical failure may occur if the recommended torque values are exceeded, if the device is used outside its intended purpose, or if non-designated (non-ROOTT) instruments/components are used.

If treatment is performed in patients with contraindications, implant failure may occur. Where implantation is performed despite absolute contraindications, the manufacturer does not accept warranty claims.

Temporary discomfort following invasive treatment is common and may occur as part of the expected post-operative course.

There is a risk that small components may be swallowed or aspirated. Due to the small size of the devices, appropriate precautions shall be taken to prevent aspiration or ingestion (e.g., use of a throat shield and/or other securing measures).

##### Side effects

Immediately after dental implant placement, activities requiring significant physical exertion should be avoided. Possible post-operative complications may include:

Temporary symptoms are:

- pain;
- swelling;
- phonetic/speech difficulties;
- gingival inflammation.

More persistent or serious complications are:

- chronic pain associated with the implant;
- persistent paraesthesia or dysaesthesia;
- loss of maxillary/mandibular ridge bone;
- localized or systemic infection;
- oroantral or oronasal fistula;
- adverse effects on adjacent teeth;
- fracture of the implant, jaw, bone, or prosthesis;
- aesthetic complications;
- nerve injury;
- Exfoliation and hyperplasia.

##### Probability of occurrence of residual risks

The probability of residual risks depends on multiple factors, including the patient's health status, pre-operative planning, surgical technique, and compliance with the Instructions for Use (IFU). The likelihood of complications may increase significantly in case of non-compliance with the IFU.

Typical post-operative side effects are common and generally expected, whereas persistent or serious undesirable effects are rare. In the PMCF study, 9.5% of patients experienced early post-operative complications, including reported events such as infection, ridge bone loss, and paraesthesia. No adverse events were reported during the 9-years follow-up period of the PMCF study.



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For patients without contraindications, the overall implantation success is high. Close cooperation between the surgeon, restorative dentist, and dental laboratory technician remains essential to achieve optimal treatment outcomes.

### Lifetime

The demonstrated lifetime of the implant is at least 9 years, based on the manufacturer's available clinical data.

A reduction in service life may occur due to patient- and treatment-related factors that are outside the manufacturer's control, including the development of contraindicating conditions after implantation (e.g., severe peri-implant bone loss/resorption, mechanical fracture of the implant body, chemotherapy or other immunosuppressive therapies, poor oral hygiene, or severe periodontal disease).

Where no contraindicating conditions are observed, TRATE AG does not recommend prophylactic explantation after 9 years. Instead, continued use may be justified based on ongoing clinical observation and follow-up outcomes, with the implant's service life supported by the accumulated post-market clinical evidence.

## 4.2. Warnings and precautions

### Warnings

Do not use the device if the primary packaging is damaged or has been opened. If the primary packaging is damaged or unintentionally opened prior to use, DO NOT USE the device.

Do not resterilize ROOTT Dental Implants.

Do not use ROOTT Dental Implants after the expiry date indicated on the packaging.

ROOTT Dental Implants and abutments are single-use. Do not reuse or reprocess implants. Reprocessing may result in infection and/or implant failure.

Aseptic handling is essential. Never use potentially contaminated components. Contamination may lead to infection.

Avoid contact of the implant with foreign substances prior to use. Do not touch the endosteal (intraosseous) part of the implant.

Use only designated ROOTT instruments for ROOTT implants and abutments.

Do not exceed the recommended insertion torque (see section "Insertion of the implant"), as excessive torque may cause bone necrosis and/or fracture of system components.

Due to the small size of the components, take precautions to prevent swallowing or aspiration. Use appropriate protective measures (e.g., throat shield and/or securing aids) to prevent aspiration of loose parts.

All ROOTT implant types have specific compatible healing abutments and abutments.

### Cautions/Precautions

It is recommended that ROOTT dental implants are used only with the designated ROOTT surgical instruments and compatible prosthetic components. Use of non-designated instruments/components may result in mechanical failure of instruments/components and/or unsatisfactory clinical outcomes.

It is strongly recommended that clinicians - both new and experienced users - complete appropriate training before using a new product or treatment method. TRATE offers a range of training courses. For further information, please visit [www.trate.com](http://www.trate.com).

Radiation therapy in patients with dental implants should be planned and prescribed with particular caution by healthcare professionals to minimize potential complications. Patients should be informed about the potential risks associated with radiotherapy following implant treatment.

## 4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

No other additional information related to the device safety, including any field safety corrective actions, is available. The devices have not been subject to any field safety corrective actions.

## 5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

### 5.1. Summary of clinical data related to equivalent device, if applicable

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The manufacturer does not claim an equivalence to establish or maintain clinical evidence, because ROOTT-specific clinical data are available and are used as the primary basis for clinical evaluation.

Nonetheless, a systematic scientific literature review is performed on a regular (annual) basis to identify, collect, and appraise clinical data related to comparable devices available on the market.

Based on the reviewed literature, the following manufacturers of titanium dental implant systems (commercially pure titanium and titanium alloys) were identified as appropriate benchmark examples for the ROOTT Dental Implant System: Neoss; Dentsply Sirona Implants (e.g., OsseoSpeed/Astra Tech, Ankylos); Nobel Biocare (e.g., TiUnite, NobelSpeedy); Biomet 3i (e.g., NanoTite, Osseotite); Intra-Lock International; Southern Implants; Sweden & Martina; Straumann (e.g., Standard Plus, Tapered Effect).

Overall, the literature on comparable devices supports that titanium dental implant systems represent a well-established technology with a predictable safety and performance profile. Reported long-term failure rates are generally low. Where complications are discussed, they are frequently described in case reports and case series, which are informative for signal detection and clinical awareness but are limited for robust incidence estimation and may be highly dependent on patient- and treatment-related factors.

The following categories of complications, side effects, and risks associated with implant therapy were identified from the reviewed literature:

- a) Technical
  - loosening of abutment/prosthesis screws;
  - fatigue fracture of implant, abutment, or prosthetic screws;
  - micro-motion at the implant–abutment interface potentially contributing to bacterial leakage;
  - gingival discoloration associated with abutment material/colour;
  - implant mobility/micromovement;
  - wear debris.
- b) Biological
  - corrosion and metal ion/particle release;
  - allergic reactions/hypersensitivity (rare);
  - soft-tissue reactions (e.g., erythema, hyperplastic tissue);
  - cytotoxicity concerns (material- and context-dependent);
  - inflammatory conditions (mucositis, peri-implantitis).
- c) Clinical / procedural
  - marginal bone loss;
  - peri-implant radiolucency;
  - mechanical and/or thermal tissue damage during site preparation;
  - tissue necrosis;
  - suppuration/bleeding associated with bacterial colonisation;
  - swelling, haematoma, pain;
  - wound dehiscence;
  - fistula formation.

Depending on study design, population, and materials, the typical 5-year implant survival rate reported in the literature is >95.6%. Complication rates vary across studies; infections and peri-implant inflammatory conditions are among the more frequently reported complications. Based on the body of evidence reviewed, titanium dental implants can be characterized as a state-of-the-art treatment option for tooth replacement, with an overall positive benefit–risk profile when used within the intended purpose and in appropriately selected patients, supported by appropriate surgical technique, prosthetic planning, and follow-up care.

### 5.2. Summary of clinical data from conducted investigations of the device before CE-marking, if applicable

No clinical investigations were conducted for the devices before CE-marking because ROOTT implants were classified as well-established technology.

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#### 5.3. Summary of clinical data from other sources, if applicable

Clinical data for the devices under evaluation are collected via an implant registry through a multicentre, open-label post-market clinical follow-up (PMCF) study of the CE-marked ROOTT Dental Implant System. The study was initiated to confirm the safety and performance of the ROOTT Dental Implant System under routine conditions of use and to support its clinical use as consistent with the state of the art. All devices belonging to the ROOTT Implant System were included in the study.

The primary endpoint was implant survival at 5 years post-implantation. Secondary endpoints included: (i) identification and evaluation of short-term complications related to the implantation procedure and/or implants; (ii) identification and evaluation of mid- and long-term implant-related complications; and (iii) assessment of potential causes of implant loss.

To minimize sponsor influence and selection bias, no additional study-specific inclusion/exclusion criteria were imposed beyond standard clinical practice. Accordingly, patient selection and contraindication assessment were performed in accordance with routine daily practice at the participating centres.

Overall, 653 ROOTT R implants were placed in 251 patients (104 male / 147 female; mean age 52 years [range 21–88]) between 2013 and 2015. The number of implants placed per patient ranged from 1 to 11. All implants were followed for 5 years. A total of 136 implants were placed using a delayed loading protocol and 115 implants using an immediate loading protocol.

The collected data demonstrate favourable clinical performance, with a cumulative implant survival rate of 98.15% for ROOTT R implants. Early post-operative findings reported at the patient level included: pain in 36 patients (14.3%), infection in 4 patients (1.6%), significant loss of alveolar ridge height in 3 patients (1.2%), inadequate oral hygiene in 2 patients (0.8%), and paraesthesia in 1 patient (0.4%). No device-related serious adverse events, unanticipated side effects, or other unexpected complications were reported during the study period.

#### 5.4. An overall summary of the clinical performance and safety

TRATE initiated its clinical registry in late 2012 as part of its PMCF activities. During the PMCF study, the safety and performance of the device are systematically monitored. The clinical data collected to date demonstrate favourable clinical outcomes. At 5 years, a cumulative survival rate of 98.15% was achieved for ROOTT R implants based on 653 implants placed in 251 patients, including 88 patients (35%) presenting with contraindications.

Medical device performance is defined as the ability of the device to achieve its intended purpose as claimed by the manufacturer. Dental implants achieve their intended purpose by replacing missing teeth. Accordingly, implant survival is considered the primary performance indicator. Implant survival is defined as the implant remaining in situ in the intended position at the time of assessment. This approach is consistent with published scientific literature, where implant performance is commonly evaluated primarily using survival rate data. Survival is generally indicative of a successful implantation outcome with maintained function and osseointegration.

An additional performance indicator is the absence of mechanical failures, such as fatigue fracture of the implant and/or superstructure. In accordance with the PMCF study data, no adverse events, including implant and/or superstructure failure due to mechanical fatigue fracture, were observed or recorded.

Medical device safety is defined as the acceptability of risks when weighed against benefits when the device is used in accordance with the manufacturer's labelling. For dental implants, safety considerations are primarily related to complication rates (side effects) and risks associated with the surgical and loading procedures. The absence of serious or severe side effects is therefore a key indicator of clinical safety. As no serious adverse events or severe side effects were reported during the PMCF follow-up period, the clinical safety profile of ROOTT R implants is considered favourable.

The only reported post-operative effects in the study population (251 patients) were transient and non-serious, including: pain (14.3%), infection (1.6%), loss of alveolar ridge height (1.2%), inadequate oral hygiene (0.8%), and paraesthesia (0.4%).

The observed low infection rate (1.6% of patients) supports an overall favourable clinical safety profile when the device is used as intended and in accordance with sterile handling and surgical best practice.

#### 5.5. Ongoing or planned post-market clinical follow-up

The manufacturer has initiated and continues to conduct several implant-related PMCF studies:

- 1) General PMCF study for ROOTT Implants and abutments
- 2) PMCF study evaluating wide-diameter R implants (4.2 mm, 4.8 mm, and 5.5 mm)
- 3) PMCF study evaluating long implants (18 mm and 20 mm) with diameters of 3.5 mm and 3.8 mm

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### 6. Possible diagnostic or therapeutic alternatives

When tooth loss or dentition defects impair masticatory function, several alternative treatment options to dental implants may be considered, depending on the extent of tooth loss and the patient's clinical condition:

- Conservative treatment (tooth preservation): Measures aimed at retaining natural teeth (typically applicable in mild cases). Where teeth can be preserved, this may be preferable; however, it is not applicable once teeth are missing.
- Removable prosthesis without anchorage (conventional denture): A non-surgical option that is generally less invasive. Limitations may include reduced chewing efficiency, discomfort, and the potential for ongoing alveolar bone resorption.
- Endodontic implants (endodontic stabilizers): Metallic extensions placed through the root apex into bone to improve root-to-crown ratio and stabilize teeth with compromised support. This may prolong tooth retention in selected cases and delay the need for extraction and replacement.
- Fixed prosthodontics (crowns/bridges): Requires suitable adjacent teeth and adequate periodontal support. Tooth preparation of adjacent sound teeth may be necessary.
- Alternative implant systems from other manufacturers: Numerous implant systems are available on the EU market; selection depends on clinical indication, practitioner preference, and device availability.

Dental implants are commonly used when tooth preservation is no longer feasible and a fixed, functionally stable replacement is desired. Where implant therapy is not possible (e.g., insufficient bone volume/quality or other limiting clinical factors), removable prostheses (with or without anchorage, as applicable) may remain a viable option.

### 7. Suggested profile and training for users

For use only by dental professionals in a clinical dental setting. Clinicians - both new and experienced users - are strongly recommended to complete appropriate training before using a new product or treatment method. TRATE offers a range of training courses. For further information, please visit [www.trate.com](http://www.trate.com).

### 8. Reference to any harmonised standards and Common Specifications (SC) applied

**Common specifications:** no

#### Harmonised standards under MDR

- EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013). EN ISO 11137-1:2015/A2:2019; harmonized 2020 03 24, A1:2021 (amendment)
- EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018). EN ISO 11737-1:2018/A1:2021;
- EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilisation process (ISO 11737-2:2019);
- EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016). EN ISO 13485:2016/A11:2021;
- EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements;
- EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021.

#### State of the art standards:

- EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants;
- EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018);
- EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices.
- EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose; Amd 1:2023
- EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems; Amendment A11:2022 + Amd 1:2023

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- EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes; Amendment A11:2022+Amd 1:2023
- ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.

#### Revision history

Rev. No.	Date issued	Change description	Revision validated by the Notified Body
1	2022-03-04	Printing date	<input type="checkbox"/> Yes Validation language: <input type="checkbox"/> No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 <sup>nd</sup> paragraph) for which the SSCP is not yet validated by the NB)
2	2022-04-04	Section 8 was managed to be in compliance with the list of applicable regulatory requirements	<input type="checkbox"/> Yes Validation language: <input type="checkbox"/> No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 <sup>nd</sup> paragraph) for which the SSCP is not yet validated by the NB)
3	2022-12-05	Section 1.2 updated: Manufacturer address changed. Section 8 updated	<input type="checkbox"/> Yes Validation language: <input type="checkbox"/> No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 <sup>nd</sup> paragraph) for which the SSCP is not yet validated by the NB)
4	2024-10-07	Content have been reviewed: <ul style="list-style-type: none"> <li>- Section 3.1 updated with delivery set information;</li> <li>- updated State of the art standards and Harmonised standard(s) under MDR to the section 8;</li> </ul>	<input checked="" type="checkbox"/> Yes (T0074241/ 30319186) Validation language: English <input type="checkbox"/> No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2 <sup>nd</sup> paragraph) for which the SSCP is not yet validated by the NB)
	Revision 2025-03-21	In section 1 updated format of address for Authorised representative according the certificate and EUDAMED; In section 9 updated latest validation by NB and added validation language: English	