Summary of Safety and Clinical Performance
ROOTT Dental Implant System
Dental abutments for ROOTT M / P Implants

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 Dental Implant System Dental abutments for ROOTT M / P Implants.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor it is intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1.	**Device trade name(s)**	**Dental abutments for ROOTT M / P Implants:** Anatomical (REF: AM); Titanium base (REF: PCOM)
1.2.	**Manufacturer's name and address**	Name: **TRATE AG** Address: Bahnhofstrasse 16, 6037 Root, Switzerland Homepage: https://www.trate.com
1.3.	**Manufacturer's Actor ID/SRN**	**SRN:** CH-MF-000019071
1.4.	**Basic UDI-DI**	76300538AbutmentsMN6
1.5.	**Medical device nomenclature description / text**	P010201, category "DENTAL IMPLANTS AND ACCESSORIES"
1.6.	**Class of device**	IIb
1.7.	**Year when the first certificate (CE) was issued covering the device**	**2017**
1.8.	**Authorised representative if applicable; name and the SRN**	TRATE UAB, Lithuania, Jonavos g. 254, 44110 Kaunas **SRN:** LT-AR-000002509
1.9.	**Notified Bodies (NB) name (the NB that will validate the SSCP) and the NB's single identification number**	BSI Group The Netherlands B.V. (2797)

2. Intended use of the device

2.1. Intended purpose

Dental implants are intended to replace missing or corrupted teeth,

a) that cannot be repaired, replaced or compensated by other means;
b) where other solutions have an undesired impact on sound teeth, or
c) where implants are desired for obtaining an optimal cosmetic result.

Dental Implants are assigned Related Superstructures - dental abutments.

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Abutments are prosthetic components connected to the implant and are intended for use as an aid in prosthetic rehabilitation. Intended use of dental abutments not depending on their types is to be connecting elements between the dental implant and the crown, to be connectors, placed on, or built into, the top of the implants to be able to fix the crown.

2.2. Indication(s) and target population(s)

Indication

The medical indications for the use of a ROOTT Dental Implants and related to them superstructure are:

- loss of teeth / missing teeth,
- replacement of damaged or ill teeth.

The concrete disease, injury, physiological condition or traumatic event leading to the loss of a tooth or to the necessity of tooth removal are manifold and do not matter, as long they are not explicitly listed in the contraindications.

Dental Abutment is the connecting element between the dental implant and the crown; they are connectors, placed on, or built into, the top of the implants to be able to fix the crown.

Patient population

Dental abutments are to be used in patients subject to dental implant treatment.

2.3. Contraindications and/or limitations

Dental abutments are only used if dental implants are placed, so all contraindications that prohibit the use of dental implants prohibit the use of the dental abutments as well. The contraindications of the dental abutments are always connected to that of the dental implants. Refer to the instructions for use for relevant types of ROOTT Dental Implants.

Limitations

To achieve the desired performance, abutments are only to be used with the products described in the Compatibility book and in accordance with the intended use for each product.

3. Device description

3.1. Description of the device

ROOTT Dental Implant System consists of ROOTT Dental Implants and Related Superstructures, i.e. healing abutments and dental abutments.

Related Superstructures, i.e. dental abutments, are produced from Titanium Alloy (Ti 6-Al 4-V ELI Grade 23).

ROOTT Dental abutments are delivered in non-sterile conditions. All ROOTT Dental Implants and Related Superstructures are single use devices. Dental abutments are directly connected to the endosseous implant intended for use as an aid in prosthetic rehabilitation.

The description of each device group is provided in the table below.

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Anatomical	**Titanium base**
REF: AM	**REF:** PCOM
Models: AM	**Models:** PCOM
Material: Titanium alloy	**Material:** Titanium alloy
Range of application: Straight regular multi-unit abutment shall be used to create screw-retained restorations	**Range of application:** Regular abutments shall be used to create screw-retained multiple restorations with CAD-CAM technology for more precise individual abutments

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

ROOTT Dental abutments do not have any novel features in comparison with the current state of the art similar products. Constructions of all products do not have any principal and critical innovations or modifications and are generally accepted at the moment as state of the art construction (current level of technique). No clinically relevant changes to any of the devices were made.

3.3. Description of any accessories which are intended to be used in combination with the device

Based on the definition provided by Article 2 (2) of MDR 2017 / 745, "Accessory" means an article which whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specially enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose.

ROOTT M / P Dental abutments do not have accessories which fall under the definition.

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

ROOTT M / P Dental abutments are intended to be used with ROOTT M / P Dental Implants.

ROOTT Dental Implant System consists of other medical devices intended to be used in combination with it that are not covered by this report, such as:

- Associated surgical instruments (e.g. insertion tools and auxiliary tools).

4. Risks and warnings

4.1. Residual risks and undesirable side-effects

Residual risks

Healing abutments and Implant abutments are an integral part of the dental implant means treatment of implant, so residual risks are directly related to the dental implant and the whole implantation success.

One hundred percent implant success cannot be guaranteed. Failure to observe the indicated limitations of use and working steps may result in failure.

Inappropriate use of the products leads to badly executed work and increased risks.

Reuse of single-use devices increases risk of contamination, cross-contamination and the whole implantation failure.

Treatment by means of implants may lead to loss of bone, biologic and mechanical failures, including fatigue fracture of implants. Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Mechanical failure could occur in case of torque force violated, the device is used in unintended way or with not ROOTT system instruments.

If the treatment is performed to the contraindicated patient, the failure of the whole implantation is possible. In case, if implantation was performed in conditions of absolute contraindications, the manufacturer does not accept any warranty requirements.

Occurrence of temporary discomfort after the invasive treatment such as typical side effects are common.

The risk of swallowed or aspirated small devices by patients is possible. Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

Inappropriate cleaning, disinfection and sterilisation procedures before the first use of dental superstructures can lead to whole implantation failure.

Infection can inhibit implant osseointegration and lead to implant failure, however it can be avoided if sterility is maintained and assured during the whole implant surgery and if proper maintenance, medication and oral hygiene is taken upon after the treatment.

Side-effects

The placement of these devices is part of an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain and swelling. During abutment placement or removal the pharyngeal reflex (gag reflex) may be triggered in patients with a sensitive gag reflex.

Abutments are part of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects similar to these associated with teeth, such as retained cement, calculus, mucositis, ulcera, soft tissue hyperplasia, soft and / or hard tissues recessions. Some patients may experience discoloration in the mucosal area such as graying.

Probability of occurrence of residual risks

Probability to experience residual risks depends on many factors, including patients health, surgery planning, etc. and can be extremely increased in case of violation of the instructions. The typical side effects are probable and common, while more persistent and undesirable side effects are rare. Only 9.5% of all patients in the PMCF study experienced early postoperative complications and recorded such side-effects as pain, infection, loss of ridge bone, and paraesthesia. No adverse events have been

observed and reported during the 5-year follow-up of the PMCF study. For people with no contraindications implantation success is excellent. Thus close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

Lifetime

The lifetime of the devices is not specifically defined. However, dental abutments are packed and delivered non-sterile in a blister that is material equivalent to the blister in which dental implants are packed and sterilised. Dental abutment lifetime can be defined as the time during which a package of the devices is not damaged to protect the device from the deterioration and alteration. Nonetheless the expected lifetime of the device packed in the blister can be expected as a minimum of 5 years based on own post market surveillance data, if the packaging, i.e. blister is not damaged or otherwise compromised. Visual inspection of the device and device package after the 5 years is highly recommended by the manufacturer to ensure integrity of the package and if there are no visual signs of damage and alterations, the lifetime can be prolonged.

4.2. Warnings and precautions

Warnings

If the primary package has been damaged or unintentionally opened before use DO NOT USE IT and contact local representative of TRATE AG for exchange via web page: www.trate.com

Because of the small size of the devices, care must be taken that they are not swallowed or aspirated by the patient. It is appropriate to use specific supporting tools to prevent aspiration of loose parts (e.g. a throat shield).

Cautions/precautions

It is recommended that ROOTT Dental implants are used only with dedicated surgical instruments and prosthetic components, as violation of this recommendation may lead to mechanical instrumental failure or unsatisfactory treatment results.

Never exceed recommended tightening torque for the screw. Overtightening of abutment may lead to a screw fracture.

Close cooperation between surgeon, restorative dentist and dental laboratory technician is essential for successful implant treatment.

It is strongly recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit www.trate.com.

ROOTT Dental Implant System must be used in accordance with the instructions for use provided by the manufacturer. It is the practitioner's responsibility to use devices in accordance with these instructions and determine if the device fits the individual patient situation.

Special attention has to be given to patients who have localised or systemic factors that could interfere with the healing process of bone, or soft tissue, or the osseointegration process (e.g. smoking, poor oral hygiene, uncontrolled diabetes, facial radiotherapy, infections in neighbourhood tooth or bone, patients passed bisphosphonate therapy).

Preoperative hard tissue and soft tissue deficit may yield a compromised aesthetic result.

All components, instruments and tooling used during the clinical and laboratory procedures must be maintained in good conditions and care must be taken that instrumentation does not damage implants or other components.

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

N/A - The demonstration of equivalence is not applicable. Equivalence is not claimed.

Nonetheless, regular scientific literature review is conducted to collect and analyse clinical data related to similar devices available on the market. According to the reviewed literature, the following titanium (commercially pure and titanium alloy) dental implant manufacturer devices can be established as similar benchmark devices for ROOTT Dental Implant system: Neoss; Dentsply Sirona Implants (OsseoSpeed, Astra Tech, Ankylos); Nobel Biocare (TiUnite, Nobel-Speedy), Biomet 3i (NanoTite, Osseotite); Intra-Lock International; Southern Implants; Sweden&Martina; Straumann (Standard Plus, Tapered effect).

In summary, literature data from similar devices demonstrated the ubiquity of design, lack of novelty, and a known safety and performance profile of the whole generic device group. Various studies have shown that failure rates over considerable time periods are extremely low, while most of the studies considering complications are published in case reports or case series, which can not be considered for a large scale estimation and are highly patient specific.

The following complications, side-effects and risks of the overall implant treatment were identified from the reviewed literature:

- Technical: loosening of abutment of prosthesis screw; fatigue fracture of implant, abutment or prosthesis screw; micro-motion between abutment and implant leading to bacterial leakage; gingival discoloration due to abutment colour; implant micromovement (mobility); wear debris;
- Biological: corrosion; metal ion/particle release; allergic reactions; hypersensitivity; mild facial erythema; hyperplastic tissues; cytotoxicity; inflammatory directions (mucositis, peri-implantitis);
- Clinical: marginal bone loss; peri-implant radiolucency; mechanical and/or thermal damage to the tissue during implant site preparation; tissue necrosis; suppuration and bleeding due bacterial colonisation; swelling; haematomas; pain; wound dehiscence; fistula.

Since the dental abutments can only be used in combination with dental implants, they are usually not singled-out in the clinical literature data. Implant survival is always directly related to the final and overall device configuration, i.e. dental implant plus abutment/healing abutment.

Depending on the details of the study and the materials used, the typical implant survival rate after 5 years is determined to be over 95.6 %. The survival rate over 95% after 5 years is an excellent result and an indication that implant-supported restorations are an excellent treatment modality. While complications are mainly infections, the rates average around 10 % of the implants and 20 % of the patients. Given these results, the extent for improving either the materials or the clinical procedures is limited. For this reason, the two well-established titanium alloys continue to be used for the overwhelming majority of implants used in dentistry, and this use seems likely to continue for the foreseeable future. The results in the reviewed studies are comparable and show similar tendencies, thus titanium dental implants, regardless of the implant material, design, surgical procedure and/or patient characteristics and potential complications, can be described as having predictable outcomes.

Ultimately, an evidently positive benefit-risk ratio of implant therapy can be derived, considering the

significantly low reported implant failures and complication cases compared with highly beneficial patient satisfaction rates, restored masticatory function, increased aesthetic requirements and patients overall physical and mental health. Therefore titanium dental implants can be confidently determined to be a state-of-the-art treatment option for patients missing teeth.

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

N/A - No clinical investigations were conducted for the devices before CE-marking.

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

Clinical data of the devices in question is collected through an implant register conducting a multicenter, open-label Post market clinical follow-up study of the CE-marked ROOTT Dental Implant System. The study plan was initiated with the objective to validate the ROOTT Dental Implant System by its practical daily use and application as state of the art with regards to its use and usability as intended. All devices belonging to the ROOTT Implant System were included in the study, without exceptions.

The primary endpoint of the study was the implant survival rate after five years postoperatively. The secondary endpoints were: the determination and evaluation of short-term complications related to the implantation procedure and/or implants; determination and evaluation of mid-term and long-term complications related to the implants; and the determination and evaluation of potential causes of implant loss.

In order to avoid manufacturer’s bias as much as possible no patient inclusion or exclusion criteria were set. No specific selection of patients was made, therefore the inclusion/exclusion criteria were those of the common and daily practice.

Since the dental abutments can only be used in combination with dental implants, they are usually not singled-out in the clinical data. Implant survival is always directly related to the final and overall device configuration, i.e. dental implant plus abutment/healing abutment. Therefore the implant survival rate data is always applicable to the overall devices configuration, including abutments, if relevant.

Overall, a total of 333 ROOTT M / P implants were placed in a total of 105 patients (46 male/59 female; mean age 61 years (range 20-85)) in the period from 2017 to 2018. Average number of implants placed in one patient: 1-6 (max. 12). All implants passed a 3-year follow-up.

Overall, a total of 333 ROOTT M / P Dental abutments were implanted in a total of 105 patients on 333 ROOTT M / P implants. The collected data so far showed excellent clinical results - a cumulative survival rate of ROOTT M Implants is 99.21% and for ROOTT P Implants - 98.75%. After the implantation 8 patients indicated pain as a postoperative complication (7.6%), 3 patients suffered from an infection (2.9%), 2 patients failed to maintain oral hygiene (1.9%).

During the follow-up years of the PMCF study no adverse events directly related to abutments, such as abutment rupture, breaking or other mechanical failures have been observed and reported. None of the patients experienced unanticipated or unexpected side-effects or complications.

5.4. As overall summary of the clinical performance and safety

TRATE started its clinical register at the end of 2012 as part of the PMCF. During the PMCF study the safety and performance of the devices are closely observed. The clinical data collected so far shows excellent clinical results. In 3 years, a cumulative survival rate of 99.21% and 98.75% of ROOTT M and ROOTT P Implants, respectively, was achieved with 333 implants and 333 dental abutments in 105 patients, despite the fact that 39% of the patients involved in the study showed clinically increased risk factors, i.e. had contraindications. The obtained PMCF study results are in line with the clinical data

available in the literature showing that ROOTT Dental Implant devices are not inferior to similar devices belonging to the generic device group available on the market.

Medical device performance is described as the ability to achieve its intended purpose as claimed by the manufacturer. Dental implants achieve their intended purpose by replacing missing teeth. Accordingly, dental abutment performance is described as their ability to aid in prosthetic rehabilitation. No reports indicating that the devices do not perform as intended have been received so far. All received clinical cases showed successful healing and formation of soft tissues; no cases of implant failure caused by infections due to soft tissue contamination have been reported. Another device performance indicator is the absence of mechanical failures, i.e. implant or superstructure fatigue fracture. In accordance with the PMCF study data no adverse events, including implant and/or abutment failure due to mechanical fatigue fracture have been observed and recorded.

Medical device safety is described as the acceptability of risks as weighed against benefits, when using the medical device according to the manufacturer's labelling. Safety concerns related to dental abutments are mainly related to complication rates (side-effects). The non-occurrence of severe side-effects is an indicator for the clinical safety of the dental abutments. Since no severe side-effects were reported during the years of the PMCF study follow-up, dental abutments for ROOTT M / P Implants can be considered of the highest clinical safety. No side-effects were reported to be specifically caused by the dental abutments. The only registered side-effects after the implant treatment procedure experienced by the patient population (105 patients) were temporary and not severe, including pain (7.6%), infection (2.9%), and failure to maintain oral hygiene (1.9%). Significantly low rates of infections - only 2.9% of patients - is a confirmation that the dental abutment is of the highest quality and cleanliness, providing protection of contamination ingress into the implant and desirable bone to implant connection and secure osseointegration.

Clinical benefits to the patient should be experienced immediately after the implant treatment and the healing process is over and should last as long as the implant is in place and retains its function. The primary intended clinical benefits to the patient are restored previous dental and masticatory function, bite force, restored esthetics, which relates to patient satisfaction and increased physical and mental health and general, health related quality of life. These benefits should be achieved and last as long as the implant is in place and no severe complications occur. Considering the results obtained from the PMCF study and data obtained from the literature, evidently positive benefit-risk ratio of implant therapy can be derived, considering the significantly low reported implant failures and complication cases compared with highly beneficial patient satisfaction rates, restored masticatory function, increased aesthetic requirements and patients overall physical and mental health. Patients treated with implants have higher levels of satisfaction, quality of life, function and bite force than patients treated conventionally, despite the possible risks associated with the implant therapy. According to the conducted benefit-risk analysis, the following conclusion was reached:

The manufacturer has considered the totality of the evidence regarding the extent of probable benefits and the extent of probable risks of a device in the benefit-risk information. All residual risks were mitigated as far as it is possible to reduce until additional risk controls are not practicable. Those implemented risk control measures are verified and considered as effective based on the issued annual PMS report which contains evidence of no incidents, recalls, adverse events, evidence of product cleanliness based on test reports, and evidence of product performance based on continuous PMCF study. All identified hazardous situations have been evaluated and all risks have been reduced to an acceptable level based upon a benefit-risk analysis. Each residual risk is acceptable, the benefits outweigh the risks by far. No additional side-effects arising from the residual risks were identified. Based on the benefits and risks it can be concluded that the multiple benefits outweigh the residual risks by far. Additional risk control

measures are not applicable and the medical device, i.e. ROOTT Dental abutments M / P can be considered safe for their intended use.

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

Post-market clinical follow-up plan is established to proactively collect and evaluate clinical data from the use in or on humans of a device which bears a CE marking and is placed on the market or put into service within its intended purpose, with the aim of confirming the safety and performance throughout the expected lifetime of the devices, of ensuring continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

The only activity that is undertaken under the post-market clinical follow-up of the ROOTT Dental Implant System devices is a PMCF study. PMCF study is planned as a prospective, multicentric, non-controlled, non-randomized, open label study to evaluate the CE-labelled ROOTT Dental Implant System under routine conditions. The primary objective of the PMCF study is to validate the ROOTT Dental Implant System by its practical daily use and application as state-of-the-art with regard to its use and usability, as intended. Clinical data is collected and evaluated in order to: confirm the safety and performance of the device throughout its expected lifetime; identify previously unknown side-effects and monitor the identified side-effects and contraindications; identify and analyse emergent risks; ensure the continued acceptability of the benefit-risk ratio; identify possible systematic misuse or off-label use of the device, with a view to verify that the intended purpose is correct. The primary endpoint of the PMCF study is the survival rate of ROOTT Dental Implants after a 5-year follow-up of at least 95%. The secondary endpoints are mainly attributed to the postoperative outcomes, such as determination and evaluation of short-term complications related to the implantation procedure and/or implants; determination and evaluation of mid-term and long-term complications related to the implants; and determination and evaluation of potential causes for implant loss. The following questions were raised regarding the safety and performance of the dental abutments:

1. Have healing abutments or abutments caused an inflammation reaction due to selected material?
2. Have healing abutments or abutments caused implant failure due to the state of cleanliness and proposed sterilisation procedure?

The PMCF Evaluation Report has been prepared after collecting 5-year follow-up data. Overall 3271 implants were included in the study. Such sample size is considered adequate to sufficiently describe a wide-range context and prevailing global tendencies. 3271 ROOTT Implants were placed in 1108 patients by 10 different experienced implantologists. To achieve a heterogeneous patient population, implants were placed in the following countries: France, Luxemburg, Spain, Hungary, Slovakia, Greece, Lithuania, Russia, India, and Israel.

The mean age of the patients was 54.17 years, with a standard deviation of 14.63 years. The youngest patient was 18 years old, the oldest patient was 93 years old. No patient drop-outs of the PMCF study have been reported so far. The population contained patients with relative contraindications, such as smokers, patients with diabetes, patients with chronic or aggressive periodontitis, patients with poor oral hygiene, patients experiencing bruxism, hypertension, hypotension or osteoporosis. This is a ratio of 41% of risk patients, while more than one contraindication in one patient was also possible.

According to the obtained PMCF study results, 333 dental abutments on ROOTT M / P implants were implanted. Out of 333 implants, only 3 (2.9%) implants failed. None of the 3 failures were reported to be directly related to the dental abutments. Also, no dental abutment failures, or adverse events related to dental abutments were observed during the years of the study follow-up.

The current PMCF study is still on-going in order to obtain long-term results. The extended goal of the study is to achieve a cumulative survival rate of at least 90% after ten years of follow-up.

The following questions will be answered with further clinical data:

- Will the goal of a survival rate over 90% after 10 years be achieved?
- What is the long-term stability of the implants in time after 10 years?

6. Possible diagnostic or therapeutic alternatives

Since Dental abutments do not have stand-alone indications and are intended to be used in combination with placed ROOTT Dental Implants, therefore when considering alternatives the indication of implants shall be taken into account.

When a lack in the dentition has an impact on the ability to chew, there are several alternative possibilities to implants, depending on the severity of teeth defects:

- Conservative Treatment: efforts to save the teeth of a patient (possible only in mild cases). When the natural teeth can be saved, this might be the best option for the patient, but is no longer an option for patients who already lost teeth.
- Prosthesis without anchorage: this prosthesis is the most painless for the patient, but such patients are commonly restricted to soft food that is easy to chew and are not protected from bone loss.
- Endodontic implants: endodontic implants are artificial metallic extensions, which can extend out through the apex of the tooth into sound bone. Endodontic implants increase the root to the crown ratio and stabilise a tooth with weakened support. It serves the patient and avoids replacement of the tooth for several years.
- Crowns / Bridges: intact teeth required in proximity of the edentulous site.
- Alternative implants from other manufacturers (there are currently more than 200 different types available on the EU market).

Dental implants are the last resort in the spectrum of possibilities of a dentist to restore the ability to chew and is commonly used when teeth conservation is no longer an option. In cases where even dental implant treatment is not possible (e.g. with too poor bone quality), a dental plate or prosthesis without anchorage is commonly still an option.

7. Suggested profile and training for users

For use only by dental professionals within the dental clinic. Recommended that clinicians, new as well as experienced users, always go through special training before using a new product or treatment method. TRATE offers a wide range of different courses. For more information, please visit www.trate.com

8. Reference to any harmonised standards and CS applied

Common specification(s)

N/A

Harmonised standard(s) under MDR

- 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, Corrected version 2018-10);
- EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
- ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer.

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2022-03-22	Printing date	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd 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	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd 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	☐ Yes Validation language: ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)