Instruction for use
ROOTT Dental Implant System
Dental Superstructures

1. Description

ROOTT Dental Implant System is a system of endosseous dental implants with corresponding abutments, healing abutments, covering and fixing screws, other prosthetic parts and surgical instruments.

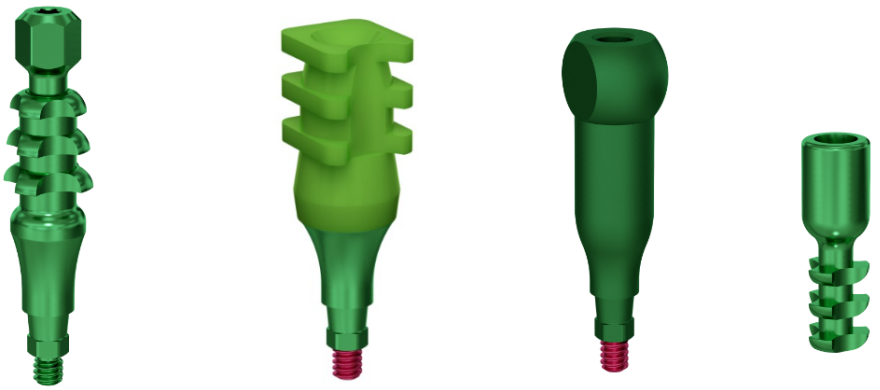
Dental Superstructures for ROOTT Dental implant system consist of transfers, scan posts, implant analogs, and abutments.

Transfers, there are metal products for indicating the position of an implant relative to the teeth and jaw structure.

Scan posts there are metal products indicating the exact position of the implant in the jaw. During the scanning process, the information about the position is transferred into digital format.

Implant Analogs there are metal or plastic parts that duplicate the implant head and show the place and direction of implant in the working model.

Abutments burn-out are used as a base to create crown or bridge.



REF No.:

Tyx, where is T - transfer, y - type, x - height,
SPCOy, where SPCO - scan post, y - type,
ANy or IAyx, where AN or IA - implant analog, y - type, x - height,
ABy or Ayx, where AB - abutment, burn-out, y - type, x - angle,
BOyx, where BO - burn-out, y - type, x - height.

Dental Superstructures are made from Titanium Alloy (Ti 6-Al 4-V ELI) or Polyoxymethylene (POM-C) and are supplied in non-sterile conditions.

Dental Superstructures available:

Transfers:

- Transfers, open tray (regular, short), for ROOTT R,
- Transfers, closed tray (direct, with cap), for ROOTT R,
- Transfer caps, for ROOTT R,
- Transfers, plastic, for ROOTT C, CS, B, BS,
- Transfers (regular, anti-rotational, short), for ROOTT C, CS, B, BS,
- Transfers, close tray, for ROOTT M, P,
- Transfers, open tray (regular, long), for ROOTT M, P,
- Transfers, close tray, for ROOTT S,
- Transfers, open tray, for ROOTT S,
- Transfers (short, regular, long), for ROOTT K.

Scan posts:

- Scan posts (laboratory, intra-oral, titanium base, Sir), for ROOTT R,
- Scan posts (laboratory, intra-oral) for ROOTT M, P,
- Scan posts (laboratory, intra-oral) for ROOTT S,
- Scan posts, intra-oral, for ROOTT K.

Implant analogs:

- Implant analogs (regular, digital) for ROOTT R,
- Implant analogs (plastic, regular, digital) for ROOTT C, CS, B, BS,
- Implant analogs (digital, regular) for ROOTT S,
- Implant analogs (regular, short, digital) for ROOTT K.

Abutments, burn-out:

- Abutment, burn-out (anti-rotational, rotational, regular), for ROOTT R,
- Abutment, burn-out (straight, angled), for ROOTT C, CS, B, BS,
- Abutment, burn-out (straight, angled), for ROOTT M, P,
- Abutment, burn-out (straight, angled), for ROOTT S,
- Abutment, burn-out (regular, short), for ROOTT K.

Basic UDI-DI information

System	**Basic UDI-DI**
ROOTT Dental Implant System	76300538ROOTTSystemRC

Device type	**Models**	**Basic UDI-DI**
Superstructures for ROOTT R		
Transfers R	TO, TOS, TOD, TR	76300538TransfersR4Q
	TC	76300538BOTransfers3W
Scan posts R	SPCO, SPCOIO, SPCOSIR	76300538ScanpostsRW7
Implant analogs R	AN, AND	76300538ImplantanalogsR22
Abutments R	AB, ABR, A1NP	76300538BOabutmentsRYJ
Superstructures for ROOTT C, CS, B, BS		
Transfers C, CS, B, BS	TRA	76300538BOTransfers3W
	TOE, TOEA, TOES	76300538TransfersC3S
Implant analogs C, CS, B, BS	ANA	76300538BOimplantanalogP6
	ANE, ANED	76300538ImplantsanalogC5U
Abutments C, CS, B, BS	BOP, A0, A15, A25	76300538BOabutmentsCXL
Superstructures for ROOTT M, P		
Transfers M, P	TRM, TOM, TOML	76300538TransfersM4E
Scan posts M, P	SPCOM, SPCOMIO	76300538ScanpostsMVV
Implant analogs M, P	ANMD, ANM	76300538ImplantsanalogM6G
Abutments M, P	ABMU, ABMUA	76300538BOabutmentsMY8
Superstructures for ROOTT S		
Transfers S	TRMS, TOMS	76300538TransfersS4S
Scan posts S	SPCOMS, SPCOMIOS	76300538ScanpostsSW9

Implant analogs S	ANMS, ANMSD	76300538ImplantanalogsS24
Abutments S	ABMUS, ABMUSA	76300538BOabutmentsSYL
Superstructures for ROOTT K		
Transfers K	TOKS, TOK, TOKL	76300538TransfersK4A
Scan posts K	SPCOIOK	76300538ScanpostsKVR
Implant analogs K	IAK, IAKS	76300538ImplantanalogsKZH
	IAKP	76300538BOimplantanalogP6
Abutments K	BOCK, BOCKS	76300538BOabutmentsKY4

Delivery set:

Five/twenty five units of one type of dental superstructures packed into the preformed 5-cells blisters with a die-cut lid. Blister packed in a protective package.

2. Intended Purpose

Dental superstructures (transfers, scan posts, implant analogs) are intended for transferring the position of the connecting interface to the working cast/model by means of an impression or digitally capturing the position of the implant in relation to the remaining teeth and soft tissues:

Transfers - indicate the position of an implant relatively to the teeth and jaw structure.

Scan posts - indicate the exact position of the implant in the jaw. During the scanning process, the information about the position is transferred into digital format.

Implant analogs - articles intended to be used in combination with ROOTT dental implants, for prediction and presentation of exact place and direction of ROOTT dental implant to the model, to assist in its function that produced superstructure will be suitable for the patient in a subject of compensation for missing or corrupted teeth.

Abutments - articles intended to be used in combination with ROOTT dental implants and ROOTT abutments, works as the burn-out base for the casting of dental crown or bridge, for accurate fulfillment of dental prosthesis which will be placed on the dental implants, and to assist in its function that produced superstructure will be suitable for the patient in a subject of compensation for missing or corrupted teeth.

3. Indications

There is no stand-alone indication for the application of the ROOTT Superstructures.

The indications for the use of the devices are strongly connected to the indications of the corresponding ROOTT Dental Implant.

All superstructures produced by TRATE have only one indication - support implant placement procedure.

Duration of use:

Transient. Normally intended for continuous use for less than 60 minutes.

4. Range of applications

Transfers R	Are intended for transferring the position of the ROOTT R dental implants to the working model: ● Open tray transfers can be used in all cases. ● Short open tray transfers can be used only in areas where there is limited space. ● Closed tray direct transfers can be used for single restoration and for multiple restorations if implants are parallel. ● Closed tray transfers with cap, can be used when there is insufficient clinical height in the distal parts of the upper and lower jaws and when implant axes diverge by up to 20°. ● Transfer caps can be used only with closed tray transfers.

Transfers C, CS, B, BS	Are intended for transferring the position of the ROOTT C, CS, B, BS dental implants to the working model: ● Rotational plastic transfers with a fixator can be used for multiple restoration and for single restoration in case of insufficient space. ● Rotational titanium transfers can be used for multiple restorations and in case of insufficient space. ● Short rotational titanium transfers can be used for multiple restorations in areas where there is limited space. ● Anti-rotational titanium transfers can be used for single restorations.
Transfers M, P	Are intended for transferring the position of the ROOTT M, P dental implants to the working model: ● Open tray transfers can be used in all cases. ● Long open tray transfers can be used for pterygoid areas. ● Closed tray transfer can be used when the implants are parallel and in areas where there is limited space.
Transfers S	Are intended for transferring the position of the ROOTT S dental implants to the working model: ● Open tray transfers can be used in all cases. ● Closed tray transfer can be used when the implants are parallel and in areas where there is limited space.
Transfers K	Are intended for transferring the position of the ROOTT K dental implants to the working model: ● Open tray transfers can be used in all cases. ● Short open tray transfers can be used only in areas where there is limited space. ● Long open transfers can be used in distal areas.
Scan posts R	Are intended for transferring the position of the ROOTT R dental implants to the working model: ● Laboratory scan posts can be used for scanning implant analog position, for printed or stone models. ● Intra-oral scan posts can be used for scanning implant position, only for intra-oral scanning. ● Titanium base scan posts can be used only for the CEREC method.
Scan posts M, P	Are intended for transferring the position of the ROOTT M, P dental implants to the working model: ● Laboratory scan posts can be used for scanning implant analog position, for printed or stone models. ● Intra-oral scan posts can be used for scanning implant position, only for intra-oral scanning.
Scan posts S	Are intended for transferring the position of the ROOTT S dental implants to the working model: ● Laboratory scan posts can be used for scanning implant analog position, for printed or stone models. ● Intra-oral scan posts can be used for scanning implant position, only for intra-oral scanning.
Scan posts K	Are intended for transferring the position of the ROOTT K dental implants to the working model: ● Intra-oral scan posts can be used for scanning implant position, only for intra-oral scanning.
Implant analogs R	Are intended for transferring the position and direction of the ROOTT R dental implants to the working model: ● Implant analogs can be used only for stone models.

	● Digital implant analogs can be used only for printed models.
Implant analogs C, CS, B, BS	Are intended for transferring the position and direction of the ROOTT C, CS, B, BS dental implants to the working model: ● Rotational plastic analogs can be used only for stone models for multiple restoration. ● Titanium analogs can be used only for stone models for single and multiple restorations. ● Digital implant analogs can be used only for printed models.
Implant analogs M, P	Are intended for transferring the position and direction of the ROOTT M, P dental implants to the working model: ● Implant analogs can be used only for stone models. ● Digital implant analogs can be used only for printed models.
Implant analogs S	Are intended for transferring the position and direction of the ROOTT S dental implants to the working model: ● Implant analogs can be used only for stone models. ● Digital implant analogs can be used only for printed models.
Implant analogs K	Are intended for transferring the position and direction of the ROOTT K dental implants to the working model: ● Implant analogs can be used only for stone models. ● Short implant analogs can be used for stone models, for cases when implants with short neck are used. ● Plastic analogs can be used only for stone models for multiple restoration.
Abutments R, burn-out	Are intended for use by the technician in process of casting the dental abutment or the prosthetic restoration on ROOTT R Dental implant: ● Anti-rotational burn-out abutments with positioning can be used for single restoration. ● Rotational burn-out abutments without positioning can be used for multiple restoration. ● Burn-out abutments can be used for single restoration in cases where individual abutment is needed.
Abutments C, CS, B, BS, burn-out	Are intended for use by the technician in process of casting the dental abutment or the prosthetic restoration on ROOTT C, CS, B, BS Dental implant ● Straight burn-out abutments can be used for single and multiple restorations. ● Angled burn-out abutments can be used in cases where the implant is placed by angle.
Abutments M, P, burn-out	Are intended for use by the technician in process of casting the dental abutment or the prosthetic restoration on ROOTT M, P Dental implant: ● Burn-out abutments can be used only for multiple restorations. ● Angled burn-out abutments can be used for multiple restorations and in cases where the implant is placed by angle.
Abutments S, burn-out	Are intended for use by the technician in process of casting the dental abutment or the prosthetic restoration on ROOTT S Dental implant: ● Burn-out abutments can be used only for multiple restorations. ● Angled burn-out abutments can be used for multiple restorations and in cases where the implant is placed by angle.
Abutments K, burn-out	Are intended for use by the technician in process of casting the dental abutment or the prosthetic restoration on ROOTT K Dental implant:

	● Burn-out abutments can be used for single and multiple restorations. ● Short burn-out abutments can be used for single and multiple restorations in narrow areas.

5. Contraindications

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

6. Patient population

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

Intended part of the body or type of tissue applied to interacted with

The upper and lower jaws in all types of bone tissue.

7. Intended users

For use only by dental professionals within the dental clinical or dental technician laboratory.

8. Summary of clinical benefit

Dental superstructures are a component of treatment with a dental implant system and / or dental crowns and bridges. As a clinical benefit of treatment, patients can expect to have their missing teeth replaced and / or crown restored.

9. Sterility

Dental superstructures are delivered in non-sterile conditions. Prior to use, they must be cleaned, disinfected and sterilized.

Cleaning and disinfection

TRATE recommend following procedure for the cleaning, disinfection and sterilization prior to use:

For cleaning, both methods can be used: manual (with ultrasonic) and automated mechanical cleaning.

If possible, a mechanical method should be used for cleaning and disinfection. A manual method should be used only if a mechanical method is not available, because of its clearly lower effectiveness and reproducibility. This also applies when using an ultrasonic bath. Perform pre-treatment both in manual and in mechanical cleaning!

For cleaning, disinfection and sterilization must be followed requirements in *Instruction for cleaning, disinfection and sterilization of non sterile and reusable medical devices from Dental Implant System ROOTT*.

Sterilization

The products can be sterilized in the autoclave at 132°C in one standard sterilization cycle with a dwell time of 3 minutes to achieve a SAL of 10^{-6}

Dental superstructures are single use devices and must not be reprocessed. Reprocessing could cause mechanical, chemical and / or biological characteristics. Reuse could cause local or systemic infection.

11. Storage, handling and transportation

The product must be stored and transported in dry conditions in the original packaging and not exposed to direct sunlight. Incorrect storage and transportation may influence device characteristics leading to failure.

12. Operating principles

Transfers

Clinical procedures:

1. Select appropriate transfer.
2. Connect the transfer to implant and hand-tighten using a dedicated screwdriver.
3. Inject around transfer with hard impression material.
4. Fill the impression tray with impression material and seat into the mouth.
5. After impression dry: for open tray transfers - unscrew screw and remove impression with transfer, for closed tray transfers - remove impression, unscrew transfer and put into impression.

Scan posts

Laboratory procedures:

1. Connect the scan post to analog and hand-tighten using a dedicated screwdriver.
2. Scan model.

Clinical procedures:

1. Connect the scan post to implant and hand-tighten using a dedicated screwdriver.
2. Scan scan post, occlusion.
3. Unscrew scan post and scan mouth without it.

Implant analogs

Laboratory procedures:

1. Attach analog with transfer: for open tray - attach analog to transfer in impression, for closed tray - attach analog to transfer and then manually insert to impression.
2. Fill the impression with dental gypsum and leave to hard. Then unscrew transfer.

Digital procedures:

1. Create a model in a chosen library.
2. Print model.
3. Put analog to model.

Abutments, burn-out

Laboratory procedures:

1. Connect abutment to analog, modify as needed.
2. Wax abutment.
3. Cast abutment.
4. When cast ready, apply final porcelain.

Clinical procedures:

1. Connect fabricated prosthesis to abutment.

13. Residual risks

Dental superstructures 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 increase 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 sterilization 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.

14. Side effects, complications with dental superstructures

The placement of these devices may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain and swelling. During superstructures placement or removal the pharyngeal reflex (gag reflex) may

be triggered in patients with a sensitive gag reflex.

Dental superstructures are only used if a dental implant is placed, so all side effects and complications that appear during the use of a dental implant can appear in the use of dental superstructures as well.

Complications may occur if ROOTT dental superstructures are used for non-ROOTT implants.

14.1. Medical emergencies in dental practice

Medical emergencies can occur in the dental practice. The emergencies that potentially could happen during the general dental treatment are listed in below:

- Bleeding, Adrenal crisis, Anaphylaxis asthma, Cardiac emergencies, Epileptic seizures, Hypoglycaemia, Red flag sepsis, Stroke, Syncope, Allergy.

Members of the dental team have a duty of care to ensure they provide an effective and safe service to their patients. A patient could collapse on any premises at any time, whether they have received treatment or not. It is therefore essential that all registrants must be trained in dealing with medical emergencies, including resuscitation, and possess up to date evidence of capability.

Planning ahead, there should be at least two people available within the working environment to deal with medical emergencies when treatment is scheduled to take place (in exceptional circumstances, the second person could be a receptionist or a person accompanying the patient.

Thus, this instruction does not contain the description of sighs, symptoms and management of medical emergency situations. Please, follow the recommendations to have trained members of the team and publicly available poster of the General Dental Council related to the Medical emergencies in dental practice.

15. Requirements for specific training and facilities 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.

16. Performance requirements and limitations

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

Performance characteristics and changes in performance

To achieve the expected performance, the ROOTT dental superstructures shall only be used with products described in this instruction for use, and in accordance with the intended use for each product. To confirm the compatibility of products which are intended to be used in combination with ROOTT Dental Implants, please check the *Compatibility book*, product catalog and dimensions on the product labelling.

It is responsibility of the clinicians to instruct the patient on all related contraindications, precautions and side effects, as well as the need to seek the services of a trained dental professional if there is any changes in performance of the implant (infection, pain, any other unusual symptoms that the patient has not been told to expect).

17. Compatibility information

Dental superstructures are compatible with ROOTT Dental Implants due to their technical characteristics. For detailed information about ROOTT Dental Implants and related to them system components compatibility see *Compatibility book.*

For further management of the ROOTT dental superstructures and subsequent placement of definitive abutment/crown/prosthesis see *Prosthetic protocols.*

Restrictions to combinations

All what is not mentioned in the *Compatibility book* is restricted to use in combination with the devices.

18. 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).

19. Cautions / Precautions

It is recommended that ROOTT dental superstructures 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 superstructure 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 localized 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 neighborhood 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.

Notice regarding serious incidents

For a patient, user and / or third party in the European Union and in countries with an identical regulatory requirements (EU Regulation 2017 / 745 on medical devices) if, during the use of this device or as a result of its use, a serious incident has occured, please report in to the manufacturer TRATE AG and to your national authority. The contact information for the manufacturer of this devices to report a serious incident is as follows:

TRATE AG
https://trate.com/warranty-and-return-form/

20. Magnetic Resonance Imaging (MRI) compatibility

Dental superstructures can not be used during any radiographic examinations and MRI scanning.

21. Material

Dental superstructures (transfers, scan posts, implant analogs and abutments burn-outs) are made from:

Titanium Alloy according to ASTM F136 and ISO 5832-3:	
Chemical components	Composition % (mass/mass)
Iron, max	0.25
Oxygen, max	0.13
Aluminium	5.5–6.50
Vanadium	3.5–4.50
Titanium	balance

Dental superstructures (transfers, implant analogs and abutments burn-outs) are made from Polyoxymethylene (POM-C) (CAS Reg. No. 24969-26-4).

22. Disposal

Safety discards potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy.

Separation, recycling or disposal of packaging materials shall follow local country and government legislation on packaging and packaging waste, where applicable.

According to the Warranty and return policy, disposed TRATE AG medical devices under specified conditions which are failed, fractured or damaged, after removal, together with the accompanying documents, can be returned to TRATE AG

under a feedback procedure. Potentially biologically contaminated product for TRATE AG determined as a returned product that was in use.

Used devices under *Warranty and return policy,* returned to a TRATE AG should have been cleaned and decontaminated by the user before shipment and labelled as such. Decontamination of used devices should be performed by *Instruction for Product Return*.

23. Information for patients

Surgeons shall provide to patients information about specified Dental implant(s). And shall inform the patient about side effects, complications for implants, contraindications, residual risks, what patients shall do or shall not do after the implantation, e.g.:

- Follow good oral hygiene: clean teeth at least 2 times a day, use dental floss;
- Avoid very hard, hot, spicy food during the healing stage;
- Avoid high physical exertion during the healing stage;
- Quit smoking because it is extremely damaging to the health of teeth and gums and slows down healing processes;
- Regularly visit the dentist and do not delay scheduled visits for observation purposes;
- The patient must contact his surgeon immediately and do not remove and dispose of any parts of superstructures of the implants themselves.

Surgeons also shall inform the patient about possible risks considering MRI treatment**.** Radiation therapy for patients with dental implants should be planned and prescribed with extreme caution by the health care professionals to avoid possible complications.

24. Validity

Upon publication of these instructions for use, all previous versions are superseded.

Please note

For the purpose of legibility, TRATE does not use ™ or ® in the text. This does not affect TRATE's rights with regards to registered trademarks.

Some products may not be available in all markets. Please contact your local TRATE representative to review the product range available.

25. Manufacturer and Authorised Representative information

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26. Symbols explanation

Available in *Instruction for explanation of symbols on ROOTT product labelling.*

CE

Change history:

Ver	Date	Change description	Responsible
01	2022-12-05	Printing date	V. Shulezhko D. Karpavicius