The following SSCP (Summary of Safety and Clinical Performance) is applicable to the following product(s):

VITA CAD-Temp®

Table of content

Revision History

Version	Changes
003	**CR-2023-218: Wording of the indications was adjusted CR-2023-221 Adjustment of the long-term temporary wearing time from 3 to 1 year**
004	**New version of Clinical Evaluation**
005	**Annual update**
006	**Annual update**

VITA Zahnfabrik
H. Rauter GmbH & Co. KG
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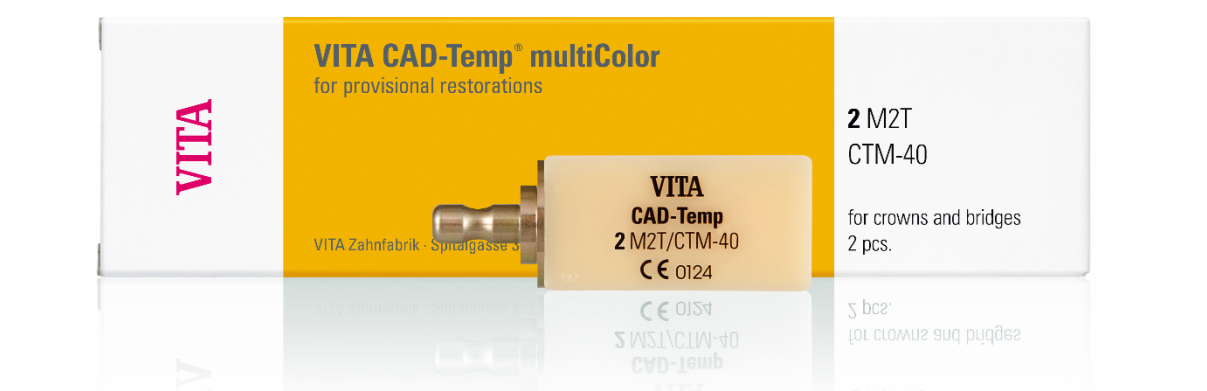
007	Annual update

Identification of the device



Device trade name	VITA CAD-Temp®
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017CD1PZ (VITA CAD Temp) ++J017CD3Q5 (VITA CAD-Temp IS) ++J017KK2RY (Mixed assortments CAD/CAM)
Medical device nomenclature (EMDN)	Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES – OTHER
Class of device	IIa
Year of first CE certificate	2007
Notified Body including identification no.	DEKRA Certification GmbH, identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA CAD Temp produtcs are polymer based crown/bridge temporaries for dental treatments.
Indication	VITA CAD-Temp is indicated for the fabrication of multi-unit, fully or partially anatomical long-term temporary bridge restorations with a span of up to two pontics and a clinical wearing period of up to one year. For CAD/CAM system requirements, please refer to the information provided by the manufacturer of the respective system.
Contraindication	• Permanent restorations with a clinical wearing period of more than three years. • In patients who are allergic to PMMA
Intended user	Dental technician, Dentist, Professional User, Rx only

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007/06.2026

Device description

a) Description of the medical device(s)

VITA CAD-Temp are machinable milling blanks for the fabrications of provisional restorations. Temporary restorations have

- prophylactic functions: avoiding the movement of abutment teeth and protection of the tooth substance against bacterial, toxic and thermal effects
- diagnostic and esthetic functions: checking of occlusion, phonetics, vertical dimension and the esthetic result
- therapeutic functions (gingival forming for controlled papillary growth for the implemented all-ceramic restorations later on, restoring implants during the healing phase, correction of temporomandibular joint disorders and correction of the occlusal plane.

Provisional restorations are worn only for a transitional period until the final denture is completed or can be inserted. Then, the provisional restoration is removed . The dentist prepares the respective defective tooth/teeth in the dentition which need replacement. The first step of the CAD/CAM technology is the intraoral acquisition of digital information on the geometry of the respective area in the dentition and the jaws, e.g. prepared tooth/teeth, neighboring teeth, opposing jaw. Alternatively, a dental model is extra-orally digitized. The CAD software processes the acquired data and enables the dental technician to design the desired restoration and a temporary restoration (crowns or bridges). The final data set is transformed into machine language. The milling machine is driven by the CAD data. It precisely mills the final dental restoration and the temporary restoration from polymer blanks, such as VITA CAD-Temp. In the next steps the lug is cut off, the surface is polished and the temporary restoration is carefully fitted on the model. For esthetic reasons, the temporary restoration can be shaded, individualized and characterized. Finally, the temporary denture is implemented via adhesive bonding.

b) Previous generations of the medical device(s)

Machinable polymers in CAD/CAM have been around for decades. There is no special predecessor product of VITA CAD-Temp in this sense.

c) Accessories / other products which are intended to be used with the medical device(s)

The following products can, but do not have to be used with the product. For a detailed description of how to use the products in combination, please refer to the product's instructions for use.

Name of accessory (manufacturer)	Short description
VITA VM LC VITA VM LC flow	Light-curing, microparticle composite for extraoral use with fixed and removable restorations – VITA CAD Temp can be individualized with the light-curing VITA VM LC and VITA VM LC flow.
VITA AKZENT LC	VITA AKZENT LC is a light-curing stain and glaze system used for characterizing all indirect restorations made of composite, polymer and hybrid ceramic, different VITA AKZENT LC EFFECT STAINS are available for this purpose.
VITA ADIVA SELF ADHESIVE (Harvard Dental)	The self-adhesive luting system with perfectly matched components for conditioning the restorative material
VITA ADIVA TE-CEM (Harvard Dental)	VITA ADIVA TE-CEM is a dual-hardening composite cement for temporary bonding.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
Therapeutic alternatives to CAD Temp can be constructions made of zirconia-reinforced lithium silicate - three-unit bridges up to the second premolar in the case of pressed ceramics, and single-tooth restorations in the case of CAD/CAM. Lithium disilicate can be used as a three-unit bridge up to the second premolar. Other therapeutic alternatives are restorations made of zirconium dioxide, gold casting or non-precious alloys. Feldspar ceramics and hybrid ceramics can be considered as therapeutic alternatives in the case of single-tooth restorations.	Risks of these therapeutic alternatives could be allergic reactions to the NEM - or gold alloy. Allergy to the adhesive cementation (or the residual monomer content present in it) may occur in restorations made of hybrid ceramics, composite, or feldspar ceramics, where this type of cementation is necessary. Gold, non-precious metal, zirconium dioxide can be conventionally cemented. Lithium disilicate and zirconium dioxide-reinforced lithium silicate can also be cemented, although adhesive cementation is recommended here for stability reasons. With conventional zinc phosphate cement, chemical noxae from phosphoric acid can cause pulp damage and the roughness of the cement can lead to local gingivitis due to increased plaque accumulation. Due to its acid components, conventional glass ionomer cement should not be used in the immediate vicinity of the pulp or the pulp should be covered in advance to protect it.

Reference to harmonized standards and CS applied

Common specifications are not used for the product VITA CAD-Temp. The following standards are applied for these products at VITA:

- *MDCG 2021-3 Custom-Made Devices Guideline*
- *ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
- *ASTM D5276-19 (2023) Standard Test Method for drop Test of Loaded Containers by Free Fall*
- *ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*
- *DIN EN 1641:2010-02 Dentistry – Medical devices for dentistry – Materials;*
- *DIN EN 22248:1993-02 Packaging Complete filled transport packages, Vertical impact test by droppinig*
- *DIN EN 62366:2021-08 Medical devices - Application 01 usability engineering to medical devices*
- *DIN EN ISO 10477:2021-02 Dentistry– Polymer-based crown and veneering materials*
- *DIN EN ISO 10993-1:2026-03 Biologische Beurteilung von Medizinprodukten - Teil 1: Anforderungen und allgemeine Grundsätze für die Beurteilung der biologischen Sicherheit im Rahmen eines Risikomanagementsystems*
- *DIN EN ISO 10993-10:2023-04 Biological evaluation of medical devices – Part 10: Tests for skin sensitization*
- *DIN EN ISO 10993-11:2018-09 Biological evaluation of medical devices– Part 11: Tests for systemic toxicity*
- *DIN EN ISO 10993-12:2021-08 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- *DIN EN ISO 10993-13:2024-04 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *DIN EN ISO 10993-14:2024-04 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*
- *DIN EN ISO 10993-16:2024-04Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables*
- *DIN EN ISO 10993-17:2026-05 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents*
- *DIN EN ISO 10993-18:2023-11 Biological evaluation of medical devices - Part 18: Chemical characterization of materials*
- *DIN EN ISO 10993-2:2023-02 Biological evaluation of medical devices – Part 2: Animal welfare requirements*
- *DIN EN ISO 10993-23:2021-10 Biological evaluation of medical devices - Part 23: Test for irritation*
- *DIN EN ISO 10993-3:2024-04 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *"· DIN EN ISO 10993-4:2017-12 Biological evaluation of medical devices– Part 4: Selection of tests for interactions with blood"*
- *DIN EN ISO 10993-5:2024-04 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *DIN EN ISO 10993-6:2024-04 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation*
- *DIN EN ISO 10993-9:2022-03 Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products*
- *DIN EN ISO 13485:2021-12 Medical devices - Quality management systems — Requirements for regulatory purposes*

· *DIN EN ISO 14971:2022-04 Medical devices - Application of risk management to medical devices*
· *DIN EN ISO 15223-1:2022-02 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*
· *DIN EN ISO 17664-1:2021-11 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices*
"· DIN EN ISO 17665:2024-09 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices"
· *DIN EN ISO 20417:2022-03 Information to be supplied by the manufacturer of medical devices;*
· *DIN EN ISO 4180:2020-03 Packaging - Complete filled tranport packages- General rules for compilation of performance test schedules*
· *DIN EN ISO 7405:2025-12 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*
· *ISO 10477:2020-10 Dentistry - Polymer-based crown and veneering materials*
· *ISO 10993-1:2025 Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*
· *ISO 13485:2016-03 Medical devices — Quality management systems — Requirements for regulatory purposes*
· *ISO 14801:2016-11 Dentistry Implants - Dynamic loading test for endosseus dental implants*
· *ISO 14971:2019-12 Medical Devices - Application of risk management to medical devices*
· *ISO 15223-1:2021-07 Amd 1:2025-03 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*
· *ISO 15223-1:2021-07 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -by the manufacturer - Part 1: General requirements*
· *ISO 20417:2021-12 Information to be supplied by the manufacturer of medical devices*
· *ISO 4180:2019-11 Packaging - Complete filled tranport packages- General rules for compilation of performance test schedules*
· *ISO 7405:2025-06 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
· *ISO TR 24971:2020-06 Medical devices — Guidance on the application of ISO 14971*
· *Use of International Standard ISO 10993-1, "Biological Evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Guidance for Industry and Food and Druf Administration Staff. September 8, 2023*
· *MDCG 2018-1 Rev.4 Guidance on BASIC-UDI and changes to UDI-DI*
· *MDCG 2019-16 Guidance on Cybersecurity for medical devices*
· *MDCG 2019-4 Timelines for registration of device data elements in EUDAMED*
· *MDCG 2019-5 Registration of Legacy Devices in EUDAMED*
· *MDCG 2019-7 Guidance on Article 15 MDR-IVDR on a Person responsible for Regulatory Compliance (PRRC)*
· *MDCG 2019-9 Summary of safety and clinical performance*
· *MDCG 2020:6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC*
· *MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD*
· *MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies*

· *MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies*
· *MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional*
· *MDCG 2021-19 Guidance note integration of the UDI within an organisation`s quality management system*
· *MDCG 2021-25 Rev. 1/ Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC*
· *MDCG 2022-4 Rev. 2 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD*
· *MDCG 2023-3 Rev. 2 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746*
· *MDCG 2023-7 Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on 'sufficient levels of access' to data needed to justify claims of equivalence*
· *MDCG 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices*
· *MEDDEV 2_7_1_rev4_en 2016-06 Guideline on Medical Devices*
· *Recommendation-NB-MED/2_5-2/Rec2_Reporting of design changes and changes of the quality system; 2.5.2 Conformity assessment procedures; Quality assurance.*

Summary of clinical data

a) Clinical studies of the medical device(s)

According to Article 61 European Medical Device Regulation, (EU) 2017/745 (MDR) the requirement to perform clinical investigations pursuant to paragraph 4 shall not apply to implantable devices and class III devices:

- which have been lawfully placed on the market or put into service in accordance with Directive 90/385/EEC or Directive 93/42/EEC and for which the clinical evaluation is based on sufficient clinical data, and
- is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device, where such a CS is available; or
- that are sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such a CS is available.

The products under evaluation have been lawfully placed on the market and put into service in accordance with Directive 93/42/EEC and the clinical evaluation of these products is based on sufficient clinical data, and is in compliance with the relevant product-specific CS for the clinical evaluation of that kind of device. Therefore, clinical investigations are not necessary to proof clinical safety and clinical evaluation is performed.

b) Clinical evaluation

Extract from the final summary of the clinical evaluation "VITA CAD-Temp and VITA CAD-Temp IS VITA Zahnfabrik" at novineon CRO GmbH
January 2024/Rev. 03: "[…] Based on the documentation provided by VITA, we conclude that the potential risks of VITA CAD-Temp are acceptable residual risks for the patient and the user.
The main risks are described in detail in the scientific literature. Thus, we conclude that the risks of the use of dental machinable polymer blanks are well-documented in the published literature, thus being known to dentists or adequately trained staff (chapter 7.5.3). When complying with all warnings and precautions, the devices under evaluation have an acceptable benefit-risk profile. […]"

c) Post market clinical follow-up

PMCF studies may not be required when the medium/long-term safety and clinical performance are already known from previous use of the device or where other appropriate post-market surveillance activities would provide sufficient data to address the risks.
The indication and treatments of VITA dental medical devices are well-known clinical procedures. The basic principles of using dental material are the same since the beginning of the 20th century.
The compliance to the DIN EN ISO 10477 applicable for polymer-based crown – and bridge material ensures the safe use of the products also in the clinical aspect.

The VITA post market monitoring collects clinically relevant data to an extent that fulfills the requirements of the European Medical Device Regulation, (EU) 2017/745 (MDR) in order to adequately assess and confirm the safety of medical devices. Therefore, no PMCF studies are required for VITA CAD-Temp® and therefore, also not part of this SSCP.

d) Conclusion of clinical performance and safety of the medical device(s)

VITA always ensures the clinical safety of its products, even after they have been placed on the market, by constantly updating the clinical evaluation of its medical products and monitoring them on the market in accordance with the requirements of the European Medical Device Regulation, (EU) 2017/745 (MDR) and according to MEDDEV 2.7/1 revision 4.

For VITA CAD-Temp® it can be said that the clinical evaluation of the products clearly states the clinical safety and performance. There is no doubt about the safety and reliability of the products. They can be used safely in the manner communicated by VITA with regard to indications, contraindications, compliance with safety instructions and residual risks.

Suggested profile and training of users

VITA dental products are designed for use by professional users. This specification is made clear by the labeling of VITA products with the symbol "Rx only". The specialist users are dentists and dental technicians who have excellent prior knowledge in the use of our products due to their many years professional training and/or university education. Follow-up training is the responsibility of the expert users and is offered by VITA specifically for VITA products. This guarantees safe handling of VITA products at every point in the application process.

Information on residual risks, undesirable effects and warnings and precautions

a) Residual Risks

Information on product-specific residual risks can be found on the VITA homepage at Downloadcenter. Produktsicherheit (vita-zahnfabrik.com)

Please be aware, that these are possible complications and residual risks of the dental product group in general, and not specific to VITA materials.

These risks must be communicated to the patient by trained personnel (e.g., dental professionals).

b) Undesirable effects

There are no known undesirable effects for the products.

c) Warnings and precautions

- **While work is in progress, wear suitable safety goggles/face protection, gloves and safety clothing. In case of formation of dust, use an extraction system or wear a face mask.**

These warnings and precautions can also be found in the corresponding instructions for use of the product(s).