VITA Zahnfabrik
H. Rauter GmbH & Co. KG
Spitalgasse 3
79713 Bad Säckingen
Germany
008/11.2026

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

VITA ENAMIC® IS HT, VITA ENAMIC® IS T

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Revision History

Version	Changes
006	**Annual update**
007	**New version of clinical evaluation**
008	**Formal Update on first page and updating standards**

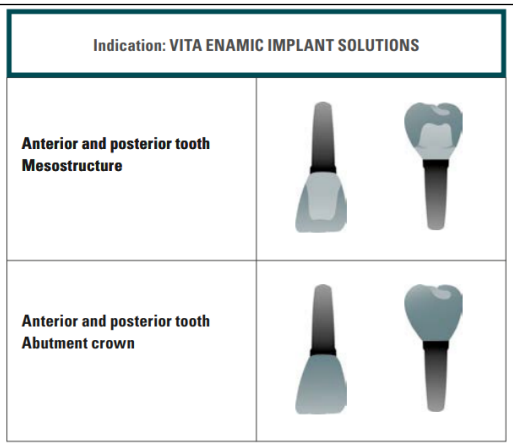
Identification of the device



Device trade name	VITA ENAMIC® IS HT, VITA ENAMIC® IS T
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017CC4Q4 (VITA ENAMIC® 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	2015
Notified Body including identification no.	DEKRA Certification GmbH, identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA ENAMIC products are ceramic materials for dental treatments.
Indication	VITA ENAMIC IMPLANT SOLUTIONS is indicated for the fabrication of mesostructures and abutment crowns on titanium bases.*

	 **Requirements for this indication:* • *A reliable adhesive bond between the VITA ENAMIC component and the titanium base:* - *Appropriate titanium base geometry (diameter, height)* • *General compliance with the requirements for all-ceramic restorations:* - *Avoidance of sharp margins and edges.* • *Cervical support of the abutment crown on the titanium base:* - *Chamfer or rectangular shoulder with a rounded inner angle and min. width of 0.6 mm*
Contraindication	• Monolithic abutment bridges • Superstructures with a highly asymmetric design and elongated extensions • Temporary seating of a VITA ENAMIC crown on the VITA ENAMIC mesostructured • Free-end restorations • Parafunctions (e.g. bruxism)
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a) Description of the medical device(s)

VITA ENAMIC® is a CAD/CAM block for single tooth restorations made of a hybrid dental ceramic. VITA ENAMIC® for KaVo ARCTICA is the name for our ENAMIC blocks with a different attachment for the processing in the milling machines of our partner KaVo. VITA ENAMIC® for Core3d is the name for our ENAMIC blocks with a different attachment for the processing in the milling machines of our partner Core3d.

VITA ENAMIC® UNIVERSAL is the name for our ENAMIC blocks with an universal attachment for the processing in all other milling machines.

VITA ENAMIC® IS are blocs for final Meso-Structures (abutment) und Abutment Crowns on a defined titanium base.

VITA ENAMIC® multiColor is made of six different layers to imitate the shade gradient of natural teeth.

VITA ENAMIC® is available in different translucency: VITA ENAMIC® T, VITA ENAMIC® HT and VITA ENAMIC® ST. The indication, contraindication and material properties are still the same, apart from their translucency, color or attachments for different milling machines.

b) Previous generations of the medical device(s)

VITA ENAMIC was the world's first hybrid ceramic of its kind and has no predecessors.

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 ENAMIC Polishing Sets	Specially developed set for time-saving and efficient polishing of VITA ENAMIC restorations. Includes all instruments for two-stage, well-coordinated polishing.
VITA Polish Hybrid	Diamond polishing paste for extraoral and final high-gloss polishing of restorations made of VITA ENAMIC, composite and polymer.

VITA AKZENT LC	Assortment for characterizing (staining technique) the shade of restorations made of VITA ENAMIC
VITA VM LC	Material for shade individualization (layering technique) of VITA ENAMIC restorations, particularly in the transparent area of anterior restorations or in the vestibular area of posterior restorations.
VITA ADIVA CERA-ETCH	Adhesive bonding of ENAMIC restorations: Extraorally only (!): etching with a 5% hydrofluoric acid gel such as VITA ADIVA CERA-ETCH
VITA ADIVA TOOTH-ETCH	Adhesive bonding of ENAMIC restorations: Starting from the enamel margins, etch the tooth substance with VITA ADIVA TOOTH ETCH (phosphoric acid gel, 37 %) for 20 sec. Spray clean for 20 sec. and dry for 20 sec.
VITA ADIVA T-BOND	Adhesive bonding of ENAMIC restorations: Apply bonding system to the tooth substance (e.g. VITA ADIVA T-BOND).
VITA ADIVA C-PRIME	Adhesive bonding of ENAMIC restorations: After drying, the etched surfaces have a whitish opaque appearance. Apply silane (e.g. VITA ADIVA C-PRIME) to the etched surfaces. Allow to evaporate completely.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
Analogous restorations made of zirconium dioxide-reinforced lithium silicate, lithium silicate, zirconium fixoid, composite, gold casting or non-precious metal alloys can serve as therapeutic alternatives for restorations with VITA ENAMIC IS.	• 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 ENAMIC IS. 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 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 dropping*
- *DIN EN 62366-1:2021-08 Medical devices - Part 1: Application of 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 Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*
- *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 10993-12:2026-02 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- *DIN EN ISO 10993-13:2010-11 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *DIN EN ISO 10993-14:2009-08 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*
- *DIN EN ISO 10993-16:2018-02 Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables*
- *DIN EN ISO 10993-17:2024-02 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*
- *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 10993-3:2026-11 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *DIN EN ISO 10993-5:2009-10 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *DIN EN ISO 10993-6:2026-08 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 18675:2023-04 Dentistry - Machinable ceramic blanks*
- *DIN EN ISO 20417:2022-03 Medical devices - Information to be supplied by the manufacturer*
- *DIN EN ISO 4180:2020-03 Packaging - Complete, filled transport packages - General rules for the compilation of performance test schedules*
- *DIN EN ISO 6872:2024-12 Dentistry - Ceramic materials*
- *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 03:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *ISO 14801:2016-11 Dentistry - Implants - Dynamic loading test for endosseous dental implants*
- *ISO 15223-1 AMD 1:2025-03 Medical devices - Symbols to be used with information to be supplied by the manufacturer*
- *ISO 15223-1:2021-07 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
- *ISO 18675:2022-05 Dentistry - Machinable ceramic blanks*
- *DIN EN ISO 20417:2022-03 Information to be supplied by the manufacturer of medical devices*
- *ISO 2206:1987-04 Packaging; Complete, filled transport packages; Identification of parts when testing*
- *ISO 4180:2019-11 Packaging - Complete, filled transport packages - General rules for the compilation of performance test schedules*
- *DIN EN ISO 7405 2025:12: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*
- *ISO 9693:2019-10 Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems*
- *ISO TR 24971 06:2020 Medical devices - Guidance on the application of ISO 14971*
- *ISO-109931-Devices-Guidance_FDA 2020*
- *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 Person responsible for Regulatory Compliance*
- *MDCG 2019-9 Summary of safety and clinical performance*
- *MDCG 2020-6 Guidance sufficient clinical evidence*
- *MDCG 2020-3 Guidance on significant changes*
- *MDCG 2020-7 Guidance on PMCF Plan Template*
- *MDCG 2020-8 Guidance on PMCF Evaluation Report Template*
- *MDCG 2021-1 Rev.1 Guidance solution until EUDAMED is fully functional*
- *MDCG 2021-19 Guidance note integration of the UDI within an organisation`s quality management system*
- *MDCG 2021-25 application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021*
- *MDCG 2022-4 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 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*
- *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 revision 4 June 2016 GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC*
- *Recommendation NB-MED/2.5.2/Rec2: Reporting of design changes and changes of the quality system*

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 prove clinical safety and clinical evaluation is performed.

b) Clinical evaluation

Extract from the final summary of the clinical evaluation "VITA ENAMIC® IS VITA Zahnfabrik H. Rauter GmbH & Co. KG" at novineon CRO GmbH July 2026/Rev. 05:
"[…]

On the basis of the documentation provided by VITA, we conclude that the potential risks of VITA ENAMIC and VITA ENAMIC IS are acceptable residual risks for the patient and the user (note: since the database on VITA ENAMIC IS is very limited and equivocal, statements regarding the risk profile and its acceptance are only possible to a confined degree compared to the clear acceptable risk profile of VITA ENAMIC). The main risks, chipping, cracking or fracture of the dental restorations manufactured

from hybrid ceramics, are described in detail in the scientific literature. On the basis of the relevant scientific literature, we conclude that the risks of the use of the generic device group of dental machinable hybrid ceramic CAD/CAM blocks are well-documented in the published literature, thus being known to dentists or adequately trained staff (CEP chapter 5.7 as well as in chapter 7.4.2.3.1). When complying with all warnings and precautions, VITA ENAMIC and VITA ENAMIC IS has 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 6872 applicable for ceramic materials and DIN EN ISO 10477 applicable for polymer-based crown and veneering materials 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 ENAMIC® IS HT, VITA ENAMIC® IS T 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 ENAMIC® IS HT, VITA ENAMIC® IS T 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

When working with the products, wear suitable safety goggles/face protection, gloves and safety clothing.



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