VITA Zahnfabrik
H. Rauter GmbH & Co. KG
Spitalgasse 3
79713 Bad Säckingen
Germany
001/05.2025

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

VITA LUMEX® UNIQUE

Table of content

Revision History

Version	Changes
001	**Initial Version**

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Identification of the device

Device trade name	VITA LUMEX® UNIQUE
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017BB4PU, ++J017BD1PU
Medical device nomenclature (EMDN)	Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES – OTHER
Class of device	IIa
Year of first CE certificate	2025
Notified Body including identification no., which validates the SSCP	DEKRA Certification GmbH, identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	The VITA LUMEX ® UNIQUE pastes are ceramic materials for dental treatments.
Indication	Esthetic finalization of monolithic restorations made of (CTE-range approx. 9,0 to 10,5 x 10-6 K-1): • Zirconium dioxide • Lithium disilicate • Feldspar ceramics Characterization of partial and full ceramic veneering with suitable dental veneering ceramics* on the following framework materials (CTE-range approx. 9,0 to 10,5 x 10 -6 K-1): • Zirconium dioxide (partially and fully veneered, e.g., with VITA LUMEX AC) • Lithium disilicate (partially and fully veneered, e.g,. with VITA LUMEX AC) • Titanium (Grad 1-5) (partially and fully veneered, e.g,. with VITA LUMEX AC)

	• Feldspar ceramics (partially veneered, e.g., with VITA LUMEX AC) Note: *) to be found in document: 10887E VITA LUMEX UNIQUE - approved veneering ceramics
Contraindication	Frameworks with unsuitable CTE values and material properties. • In patients with allergies/sensitivities to the ingredients. • With insufficient space.
Intended user	Dental professionals only: dentists and dental technicians (Rx only).

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Device description

a) Description of the medical device(s)

VITA LUMEX UNIQUE is a ready-to-use dental ceramic material in paste form for the esthetic finalization of crown and bridge frameworks made of yttrium-stabilised zirconium dioxide, lithium disilicate and feldspar ceramic. Small changes in shape and surface structure and the addition of contact points are possible.

b) Previous generations of the medical device(s)

Veneering ceramics have been on the market in all possible variations for many decades. Special predecessor products of VITA LUMEX UNIQUE do not exist in this form.

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

Name of accessory	Short description
VITA LUMEX® UNIQUE LIQUID	Used for the remaining ceramic materials to achieve a more fluid mixture for processing. Mixing of Effect Powders.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
VITA LUMEX UNIQUE is used for the esthetic finalization of dental restorations. They are intended to enhance the naturalness and aesthetics of the dental restoration.	There is no risk other than not using these materials, except that the aesthetics of the restoration may be minimized.

Reference to harmonized standards and CS applied

Common specifications are not used for the product VITA LUMEX UNIQUE. 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 Standardt 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 02:2010 Dentistry – Medical devices for dentistry – Materials;*
- *DIN EN 22248 02:1993 Packaging Complete filled transport packages, Vertical impact test by droppinig*
- *DIN EN 62366 08:2021 Medical devices - Application 01 usability engineering to medical devices*
- *DIN EN ISO 10993-1 05:2021 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management system*
- *DIN EN ISO 10993-10 04:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitization*
- *DIN EN ISO 10993-11 09:2018 Biological evaluation of medical devices– Part 11: Tests for systemic toxicity*
- *DIN EN ISO 10993-12 08:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- *DIN EN ISO 10993-13 11:2010 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *DIN EN ISO 10993-14 08:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*
- *DIN EN ISO 10993-16 02:2018 Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables*
- *DIN EN ISO 10993-17 02:2024 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (*
- *DIN EN ISO 10993-18 11:2023 Biological evaluation of medical devices - Part 18: Chemical characterization of materials*
- *DIN EN ISO 10993-2 2:2023 Biological evaluation of medical devices – Part 2: Animal welfare requirements*
- *DIN EN ISO 10993-23 10:2021 Biological evaluation of medical devices - Part 23_ Test for irritation*
- *DIN EN ISO 10993-3 02:2015 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *DIN EN ISO 10993-5 10:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *DIN EN ISO 10993-6 09:2017 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*
- *DIN EN ISO 10993-9 03:2022 Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products*
- *DIN EN ISO 13485 12:2021 Medical devices – Quality management systems – Requirements for regulatory purposes*
- *DIN EN ISO 14971 04:2022 Medical devices – Application of risk management to medical devices*
- *DIN EN ISO 15223-1 02:2022 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*
- *DIN EN ISO 20417 03:2022 Information to be supplied by the manufacturer of medical devices;*
- *DIN EN ISO 4180 03:2020 Packaging - Complete filled tranport packages- Gerneral rules for compilation of performance test schedules*
- *DIN EN ISO 6872 12:2024 Dentistry - Ceramic materials*

- *DIN EN ISO 7405 03:2019 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- *DIN EN ISO 9693 02:2020 Dentistry – Compatibility testing for metal-ceramic and ceramic-ceramic systems*
- *ISO 10993-1 10:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*
- *ISO 13485 03:2016 Medical devices — Quality management systems — Requirements for regulatory purposes*
- *ISO 15223-1 07:2021 Amd 1 03:2025 Medical devices - Symbols to be used with information to be supplied by the manufacturer*
- *ISO 2206 04:1987 Packaging - Complete filled transport packages-Identification of parts when testing*
- *ISO 7405 10:2018 Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*
- *ISO 9693 10:2019 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_6872_08:2024 -Dentistry - Ceramic materials*
- *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_en*
- *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 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*
- *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*
- *MEDDEV 2_7_1_rev4_en 06:2016*
- *Recommendation-NB-MED-2_5-2_Rec2_Reporting_of_design_changes_and_changes_of_the_quality*

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 are used for the fabrication of tooth crowns 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 "Veneering Ceramics and Stains VITA Zahnfabrik H. Rauter GmbH & Co. KG" at novineon CRO GmbH April 2025/Rev. 05:"[…] Based on the documentation provided by VITA, we conclude that the potential risks of the Veneering Ceramics and Stains are acceptable residual risks for the patient and the user. The main risks, chipping or debonding of the dental restorations manufactured from dental ceramics, are described in detail in the scientific literature. Thus, we conclude that the risks of the use of dental ceramics, indications, contraindications and warnings, described in the IFU are well-documented in the published literature and the state-of-the-art, thus being known to dentists or adequately trained staff (chapter 7.4.2.2.1). When complying with all warnings and precautions, Veneering Ceramics and Stains 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 6872 applicable for Dental ceramics 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 LUMEX® UNIQUE 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 LUMEX® UNIQUE 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).