VITA Zahnfabrik
H. Rauter GmbH & Co. KG
Spitalgasse 3
79713 Bad Säckingen
Germany
003/06.2023

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

VITA AMBRIA®

Table of content

Revision History

Version	Changes
001	Initial version
002	New revision of clinical evaluation
003	Yearly update

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Identification of the device

Device trade name	VITA AMBRIA®
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017DD1Q6
Medical device nomenclature (EMDN)	Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES – OTHER
Class of device	IIa
Year of first CE certificate	2020
Notified Body including identification no.	DEKRA Certification GmbH, Identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA AMBRIA are ceramic materials for dental treatments.
Indication	• Occlusal veneers (Table Tops)*, veneers* • Inlays*, onlays*, partial crowns* • Crowns in the anterior and posterior area • Three-unit bridges in the anterior tooth region up to the second premolar as a terminal pillar • Single tooth restorations as implant suprastructures for anterior and posterior teeth • Three-unit bridges as implant suprastructures up to the second premolar on implant abutments

	• Single tooth mesostructures in the anterior and posterior areas • Abutment crowns in the anterior and posterior areas
Contraindication	• In cases of inadequate oral hygiene • In cases of inadequate preparation results (such as tangential preparation, for example) • Insufficient hard tooth substance In cases of insufficient space available • Hyperfunction: for patients diagnosed with excessive occlusal function, in particular teeth grinders and clenchers • Restoring devitalized teeth of patients with hyperfunctions • Endodontic crowns • Posterior bridges in the area of molars • In cases of bridges with more than three units • Inlay-retained bridges / Maryland bridges • Cantilever bridges • In patients with allergies or sensitivities to the ingredients • Conventional or self-adhesive incorporation of inlays, onlays, veneers, partial crowns and occlusal veneers (Table Top) • Temporary seating of restoration
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a) Description of the medical device(s)

The press ceramic system includes press ceramic pellets in three levels of translucency (T/HT/ST/MO) and two geometries (S, L), muffle system, investment material and liquid, as well as press plungers.

b) Previous generations of the medical device(s)

VITA PM 9 is a previous press ceramic system and based on the fine-structure veneering ceramic VITA VM 9.

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 Easyshade V	For digital shade determination, use VITA Easyshade V, and for visual shade determination, use a VITA shade guide.
Modeling or milling wax	For modeling, use a residue-free combustible modeling or milling wax.
VITA AMBRIA INVEST P + F and MUFFEL SYSTEM	For investing, use the coordinated investment material system VITA AMBRIA INVEST P + F and the VITA AMBRIA MUFFEL SYSTEM.
VITA VACUMAT 6000 MP and VITA AMBRIA PLUNGER	For pressing, use VITA AMBRIA Pellets, the combipress unit VITA VACUMAT 6000 MP and the disposable press plunger VITA AMBRIA PLUNGER.
VITA LUMEX AC	Veneer your reconstructions with the veneering ceramic VITA LUMEX AC, which is ideally matched to VITA AMBRIA.
VITA AKZENT PLUS	Characterize and glaze restorations with the VITA AKZENT PLUS stains/glazing materials.
VITA SUPRINITY Polishing Set	Polish restorations with the recommended VITA SUPRINITY Polishing Set.
VITA ADIVA LUTING SOLUTIONS	Bond restorations fully or self-adhesively with VITA ADIVA LUTING SOLUTIONS.

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 VITA AMBRIA can be restorations made of zirconia-reinforced lithium silicate/ZLS, in the case of pressed ceramics three-unit bridges up to the second premolar, and in the case of CAD/CAM restorations only single-tooth restorations. Hybrid ceramics, composites and feldspar ceramics can only be used as an alternative for single-tooth restorations. Zirconium oxide, gold casting and non-precious alloys can represent further therapeutic alternatives according to the intended indications and can also be used beyond 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 AMBRIA. 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*
- *DIN EN 1641 10:2009 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 08:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (*
- *DIN EN ISO 10993-18 03:2021 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 10993-3 02:2015 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *DIN EN ISO 10993-4 12: 2017 Biological evaluation of medical devices– Part 4: Selection of tests for interactions with blood*
- *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 01:2019 Dentistry – Ceramic materials*

- *DIN EN ISO 7405 03:2019 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- *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 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 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_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 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*
- *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 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 AMBRIA VITA Zahnfabrik H. Rauter GmbH & Co. KG" at novineon CRO GmbH June 2022/Rev.03: "[…] On the basis of the documentation provided by VITA, we conclude that the potential risks of the VITA AMBRIA are acceptable residual risks for the patient and the user. The main risks chipping or fracture of the dental restorations manufactured from lithium-disilicate glass-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 zirconia-reinforces lithium disilicate glass ceramic glass pellets are well-documented in the published literature, thus being known to dentists or adequately trained staff. When complying with all warnings and precautions, VITA AMBRIA 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 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 AMBRIA® 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 AMBRIA® 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.**
- **Only perform work under an extraction unit.**
- **Wear light face mask when working.**

The following VITA AMBRIA products or accessories require hazard identification:		
VITA AMBRIA INVEST P	Contains quartz and cristobalite. Causes damage to the lungs through prolonged or repeated exposure. Route of exposure: inhalation. Do not inhale dust. If you feel unwell, contact a doctor. Dispose of contents in accordance with local regulations.	
VITA Firing Paste	May cause cancer by inhalation. Causes skin irritation. For commercial use only. Wear protective gloves/protective clothing/eye and face protection. Use personal protective equipment as required. Special treatment: remove contaminated clothing and wash before wearing again. Keep locked up. Dispose of contents/container in accordance with local/regional/national/international regulations. Hazardous dust is formed when crushing in the dry condition (after firing).	 

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