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

Liquids for Veneering Ceramic, VITA NP BOND, VITA VM®13, VITA VMK 95, VITA VMK Master®

Table of content

Revision History

Version	Changes
001	**Initial version**
002	**Yearly update**
003	**Yearly update**
004	**New clinical evaluation Yearly update**

Identification of the device

Device trade name	Liquids for Veneering Ceramic, VITA NP BOND, VITA VM®13, VITA VMK 95, VITA VMK Master® **Please note, that VITA VMK 95 is not available in the EU*
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017BB1PN (VITA NP BOND, VITA VM 13, VITA VMK 95, VITA VMK Master) ++J017BD1PU (Liquids)
Medical device nomenclature (EMDN)	Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES – OTHER
Class of device	IIa
Year of first CE certificate	VITA VM 13: 2003
	VITA VMK 95: 1995
	VITA VMK Master: 2009
	VITA NP BOND: 2014
Notified Body including identification no.	DEKRA Certification GmbH, Identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA VM 13, VITA VMK 95, VITA VMK Master and VITA NP BOND products are ceramic materials for dental treatments.
Indication	VITA VM 13 VITA VM 13 can be used for metal-veneered substructures with a high proportion of gold or reduced proportion of precious metal, and for palladium based and non-precious alloys with a CTE value (26-600 °C) of 13.8 – 15.2 10^{-6} K^{-1}. VITA VMK 95 VMK 95 is a veneering ceramic for metal substructures made of high gold content, reduced gold content and palladium-based as well as non-precious alloys in the conventional CTE range (13.8–15.2 10^{-6} K^{-1}). VITA VMK Master VITA VMK Master is a feldspar veneering ceramic for metal substructures in the conventional CTE range of 13.8 – 15.2 10^{-6} K^{-1}. VITA NP BOND VITA NP BOND Paste can be used with all non-precious metal alloys such as cast, CAD/CAM or laser-sintered alloys. It is suitable for CTE (600 °C) 13.8 –15.2 10^{-6} K^{-1}.
Contraindication	VITA VM 13 • Substructures out of the recommended CTE range • Parafunctions (e.g. bruxism) • If minimum layer thicknesses of the ceramics cannot be adhered to • In cases of insufficient oral hygiene VITA VMK 95 • Substructures out of the recommended CTE range • Parafunctions (e.g. bruxism) • If minimum layer thickness of the ceramics cannot be adhered to • In cases of insufficient oral hygiene VITA VMK Master • substructures out of the recommended CTE range • parafunctions (e.g. bruxism) • if minimum layer thicknesses of the ceramics cannot

	be adhered to • in cases of insufficient oral hygiene VITA NP BOND None known.
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a) Description of the medical device(s)

Veneering ceramics are used to veneer a wide variety of framework materials in the dental field. The CTE of substructure materials and veneering materials must be coordinated accordingly. The use on the corresponding substructure materials is indicated as indication or to use material in the corresponding accompanying documents of the products.

b) Previous generations of the medical device(s)

Veneering ceramics have been on the market in all possible variations for many decades. VITA VMK Master is a further development of VITA VMK 95. The CTE range is the same. Compared to VITA VMK 95, VITA VMK Master is the veneering ceramic for all metal substructures in the corresponding CTE range.

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

VITA VMK 95:

Name of accessory (manufacturer)	Short description
VITA MODELLING FLUID	Liquid for mixing the ceramic masses.
VITA PASTE OPAQUE LIQUID	Liquid for mixing the ceramic masses.
VITA OPAQUE FLUID	Liquid for mixing the ceramic masses.
VITA MODELLING FLUID RS	For modelling over an extended period. For mixing any dentin, incisal or additional materials
VITA Modisol	The model is then insulated with VITA MODISOL for subsequent correction of the basal surface

VITA VM 13:

Name of accessory (manufacturer)	Short description
VITA MODELLING FLUID RS	Red special liquid for mixing all dentine, incisal and additional materials. The smooth consistency of VITA MODELLING FLUID RS allows for extended and wet processing, while ensuring good stability. The fluid is particularly suited for large-sized restorations and multi-unit bridges.
VITA VM OPAQUE FLUID	Especially for mixing the VITA VM powder opaque materials. Note: Cannot be used for mixing the dentine materials!
VITA VM PASTE FLUID	Liquid for mixing the VITA VM paste opaque materials.
VITA MODELLING FLUID	For mixing all dentine, incisal and additional materials. VITA MODELLING FLUID avoids rapid drying of the ceramic material. The liquid also causes increased plasticity when layering.
VITA VM MODELLING LIQUID	For mixing BASE DENTINE, TRANSPA DENTINE, ENAMEL and additional materials. VITA VM MODELLING LIQUID provides excellent stability characteristics during layering and allows faster evaporation of the liquid. Perfectly suitable for the fabrication of small restorations or for processing without the permanent use of an extraction unit.
VITA HIGH SILVER MODELLING LIQUID	Special anti-greening liquid for high silver content alloys (silver content > 30 %).
VITA MODELLING LIQUID 30M	For mixing dentine and enamel materials when modelling VITA porcelains for long periods with firing temperatures of over 900°C.
VITA CERAMICS ETCH	Can be used for etching the surface of the ceramic (extraoral).

VITA SPRAY-ON LIQUID	The wash opaque can also be applied using the VITA SPRAY-ON procedure. Mix the powder wash opaque with VITA SPRAY-ON LIQUID in the appropriate glass container and spray homogeneously onto the substructure surface.
VITA Modisol	Insulate the model once more with the VITA Modisol pen. The interdental spaces and the basal surface of the pontic must be filled with BASE DENTINE.
VITA AKZENT PLUS	If required, the entire restoration can be coated with VITA AKZENT PLUS GLAZE and then individualization can be carried out using the VITA AKZENT PLUS stains.

VITA VMK Master:

Name of accessory (manufacturer)	Short description
VITA MODELLING FLUID	For mixing all dentine, incisal and additional materials. VITA MODELLING FLUID avoids rapid drying of the ceramic material. Increased plasticity during layering is achieved.
VITA MODELLING FLUID RS	Red special liquid for mixing all dentine, incisal and additional materials. The smooth consistency of VITA MODELLING FLUID RS allows extended and wet processing, while ensuring good stability. The fluid is particularly suited for large-sized restorations and multi-unit bridges.
VITA OPAQUE FLUID	For mixing all powder opaque materials. Note: Cannot be used for mixing the dentine materials!
VITA PASTE OPAQUE LIQUID	Liquid for diluting the consistency of the paste and, if required, for re-mixing the paste opaque materials.
VITA HIGH SILVER MODELLING LIQUID	Anti-greening liquid for high silver content alloys (silver content >30%).
VITA MODELLING LIQUID 30M	For mixing dentine and enamel materials when modelling VITA porcelains for long periods with firing temperatures of over 900°C
VITA AKZENT PLUS	For reproducing natural shade effects and anomalies during surface characterization. The stains feature a fine-grain structure, intense shade and are slightly fluorescent and particularly stable and can be mixed with one another.
VITA INTERNO	Materials for perfect reproduction of very subtle, in-depth shade effects. They feature intense shades and high fluorescence to achieve exeptional brilliance of the shades. VITA INTERNO materials can be washed in (in the unmixed state) or mixed with OPAQUE DENTINE, DENTINE, ENAMEL and TRANSLUCENT.

VITA SPRAY ON	Opaque paste is applied in the same way to mask the surface of the clean and dry substructure or, alternatively, sprayed on with VITA SPRAY-ON.
VITA Modisol	It is recommended to insulate the bridge with VITA Modisol before it is placed on the model. This way, any material applied in the basal area will not stick to the model.
VITA VACUMAT 6000 M	Aavailable in a modern, compact and ergonomic design, the fully automatic VITA VACUMAT 6000 M for all dental ceramic firings, offers consistent firing results with convincing quality, thanks to the innovative firing technology.
VITA Linearguide 3D-MASTER® / VITA Toothguide 3D-MASTER®	With the VITA Linearguide 3D-MASTER or the VITA Toothguide 3D-MASTER, you can determine the correct tooth shade quickly and precisely.
VITA Easyshade® V	VITA Easyshade V is a digital shade measurement device for determining the shade of natural dentition, bleached teeth and ceramic restorations precisely, quickly and independently of the ambient environment. The measurement results are displayed in the established standard shade systems VITA classical A1 -D4 and VITA SYSTEM 3D-MASTER, as well as in the form of VITABLOCS shades and bleached shades, in accordance with the American Dental Association (ADA).
VITA classical A1–D4® shade guide	The original - for the determination of the tooth shade in the VITA classical A1–D4 shades

VITA NP BOND:

Name of accessory (manufacturer)	Short description
VITA VM 13	VITA NP BOND Paste is a ceramic material that balances the differing coefficients of thermal expansion between non-precious-metal alloys and ceramics (such as VITA VMK MASTER or VITA VM 13, for example). It also protects the ceramic from metal oxides emitted from the metal.
VITA VMK MASTER	VITA NP BOND Paste is a ceramic material that balances the differing coefficients of thermal expansion between non-precious-metal alloys and ceramics (such as VITA VMK MASTER or VITA VM 13, for example). It also protects the ceramic from metal oxides emitted from the metal.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
The therapeutic alternative of veneers can be a purely monolithic metal restoration without subsequent staining or further characterization.	The risk of a purely monolithic restoration compared to a classical veneer with e.g. VITA VM 13 is a less aesthetic appearance - which could play a role especially in single-tooth restorations in the anterior region.

Reference to harmonized standards and CS applied

Common specifications are not used for the products VITA VM 13, VITA VMK 95, VITA VMK Master and VITA NP BOND. 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 14971 12:2019 Medical devices – Application of risk management to medical devices*
- *ISO 15223-1 07:2021 Amd 1 03:2025 Medical devices - Symbols to be used with information to be supplied by the manufacturer*
- *ISO 15223-1 07:2021 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*
- *ISO 20417 12:2021 Information to be supplied by the manufacturer of medical devices*
- *ISO 2206 04:1987 Packaging - Complete filled transport packages-Identification of parts when testing*
- *ISO 4180 11:2019 Packaging - Complete filled tranport packages- Gerneral rules for compilation of performance test schedules*
- *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 EUDAME*
- *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*
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*Following standards are not applicable for VITA NP BOND:

- DIN EN ISO 6872
- ISO 6872
- DIN EN ISO 9693
- ISO 9693

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 (VITA VM 13, VITA VMK 95, VITA VMK Master and VITA NP BOND) 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 "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 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 VM 13, VITA VMK 95, VITA VMK Master and VITA NP BOND 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 VM 13, VITA VMK 95, VITA VMK Master and VITA NP BOND 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).