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

VITA VM®LC, VITA VM®LC flow, VITA VM®LC Primer

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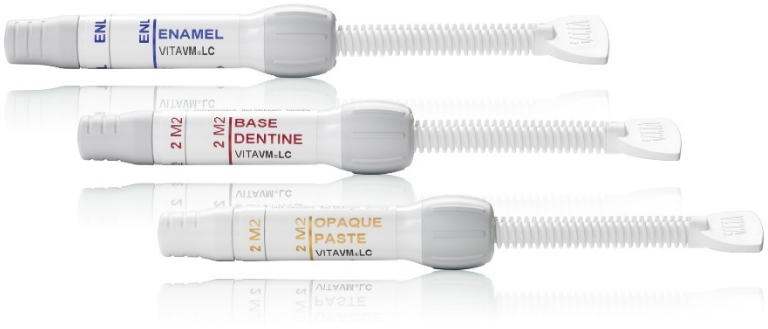
Revision History

Version	Changes
001	**Initial version**
002	**Transfer to new form**
003	**Yearly update**
004	**Yearly update** **New clinical evaluation**
005	**Yearly update**

This SSCP has been electronically signed and approved by Müller, Sindy on 13.06.2025

Identification of the device



Device trade name	VITA VM®LC, VITA VM®LC flow, VITA VM®LC Primer
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017BC1PR
Medical device nomenclature (EMDN)	Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-MADE DENTAL DEVICES – OTHER
Class of device	IIa
Year of first CE certificate	2003
Notified Body including identification no.	DEKRA Certification GmbH, identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITAVM® LC products are veneer resin materials for dental prosthesis. (VITA VM LC PRIMER / VITA VM LC MODELLING LIQUID / VITA VM LC OPAQUE LIQUID is an accessory of the VITA VM LC veneering resin.)
Indication	**<u>Veneering composites:</u>** • Full and partial veneering of metal frameworks: crowns, bridges, telescopic crowns, implant suprastructures • Inlays, veneers ***Application areas:*** • Individualization and layering-over VITA ENAMIC • Veneering partially yttrium-stabilized ZrO2 frameworks (CTE 10.0 - 10.5 · 10^{-6} · K^{-1}), such as VITA YZ SOLUTIONS

	• Individualization of VITA acrylic teeth • Reproduction of gingival areas • Veneering of removable and partially removable dentures (according to the manufacturer's information) made of polyether ether ketone (PEEK) with a filler content of up to 20%, such as BioHPP/Bredent • PEEK-OPTIMA LT1 polymer, such as Juvora, InnoBlanc Medical ***Long-term temporaries:*** • Individualizing and layering of long-term temporaries made from VITA CAD-Temp • Metal-free crowns and three-unit anterior bridges made from VITA VM LC **VITA VM LC Primer I and II:** • Adhesive bonding of metal substructure surfaces (non-precious metal alloys, PM alloys, titanium) with (meth-)acrylate-based resins/composites • Adhesive bonding of ZrO2 substructure surfaces with (meth-)acrylate-based resins/composites • Adhesive bonding of cross-linked composites/resins such as VITA CAD-Temp or of high-performance polymers (PEEK, PEKK) with (meth-)acrylate-based resins/composites
Contraindication	**Veneering composites** • Occlusal dysfunctions or parafunctions, such as bruxism • All alloys and resin framework materials may be used for frameworks, which are suitable for veneering with composite, according to the manufacturer’s information **VITA VM LC Primer I and II** • Applications that are not listed under indications
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a. Description of the medical device(s)

The VITA metal-polymer composite system serves for the production of an adhesive layer between metal crowns and bridge frames and the tooth-colored composite material. VITAVM® LC flow is a composite with low viscosity and thixotropic behavior.

VITA VM®LC PRIMER I+II are bonding agents for reliable bonding of VITA VM LC veneering composites to dental substructure materials.

b. Previous generations of the medical device(s)

VITA VM LC is the further development of VITA ZETA and the previous VITA K&B polymer veneering material.
For the VITA VM LC Primer I and II, there are no previous or similar generations of the device within the VITA product families.

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 OPAQUE LIQUID	Mixing liquid for OPAQUE powder. OPAQUE LIQUID must not be used together with OPAQUE PASTE paste material.
VITA VM LC SEPARATOR	Liquid for separating plaster models against resin. Application: Use a disposable brush to apply VITA VM LC SEPARATOR to the dust-free and dry plaster model to achieve a glossy surface. Leave to dry for 5 minutes.
VITA VM LC MODELLING LIQUID	Application is easier if the modelling instrument or the brush is wetted with a very small quantity of liquid. Use very sparingly. The liquid must not be used to thin the powders. To be used for wetting the veneering materials after adjustments made by grinding.

	Ensures bonding of VITA VM LC with, for example, VITA acrylic teeth and VITA CAD-Temp.
VITA VM LC CLEANER	Cleaning liquid should be used to remove non-polymerized VITA VM LC materials from instruments. Hardened material residues can be partially dissolved with VITA VM LC OPAQUE LIQUID.
VITA VM LC GEL	To prevent formation of an inhibition layer during final polymerization and to facilitate finishing. (only extraoral use)
VITA VM LC Primer I and II	VITA VM LC PRIMER I and II are bonding agents for reliable bonding of veneering composites to dental substructure materials.
VITA ADIVA C-PRIME	Single-component silane bonding agent.
VITA porcelain mixing plate	For light-curing materials
VITA CERAMICS ETCH	(for extraoral use only!) Hydrofluoric acid gel, 5%, for etching silicate ceramics, red colored.
VITA ENAMIC	Recommended substructure
VITA YZ SOLUTIONS	Recommended Substructure
VITA CAD-Temp	Recommended Substructure
GC METAL PRIMER Z, GC METAL PRIMER II	Recommended Primer component
Kuraray Alloy Prime	Recommended Primer component
Heraeus Kulzer Signum Metal Bond I + II	Recommended Primer component
Shofu M.L. Primer	Recommended Primer component
Shofu MZ Primer Plus	Recommended Primer component
3M Espe Rocatec with Espesil	Recommended Primer component
VITA ENAMIC Polishing Set technical	For polishing of restauratations containing VM LC materials
VITA ADIVA® F-CEM	The dual-curing luting composite VITA ADIVA® F-CEM is recommended for bonding. Please adhere to the working instructions.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
The veneering composite VITA VM LC is used to individualize hybrid ceramic, composite and polymer materials. Alternatively, monolithic work can also be carried out with the corresponding restorative materials, i.e. only finished and finally polished. It is also possible to characterize purely superficially with the composite stains VITA AKZENT LC or similar light-curing stain systems if this is required for functional reasons. In the case of partial and complete dentures, the free and attached gingiva can also be reproduced with colored cold and hot polymers as part of the pressing or pouring process.	Risks of these therapeutic alternatives could be allergic reactions to the adhesive cementation (or the residual monomer content present in it) when using composite where this type of cementation is necessary.

Reference to harmonized standards and CS applied

Common specifications are not used for the product VITA VM LC and VITA VM LC flow. 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 10477 02:2021 Dentistry– Polymer-based crown and veneering materials*
- *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 7405 03:2019 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- *ISO 10477 10:2020 Dentistry — Polymer-based crown and veneering materials*
- *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 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 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*
- *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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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 VM CC VITA VM LC VITA Zahnfabrik H. Rauter GmbH & Co. KG" at novineon CRO GmbH June 2024/Rev.04: "[…] Based on the documentation provided by VITA, we conclude that the potential risks of the VITA VM CC, VITA VM LC and VITA AKZENT LC are acceptable residual risks for the patient and the user. The main risks, chipping or fracture of the temporal dental restorations manufactured and suspicion of toxicity effect of raw materials, are described in detail in the scientific literature. The trained dental technician and/or dental physician knows how to handle, process, and combine these raw materials to manufacture a safe and esthetic dental restoration with a good esthetic appearance. Thus, we conclude that the risks of the use of veneering materials, 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 7.4.3.2.1). When complying with all warnings and precautions, VITA VM CC, VITA VM LC and VITA AKZENT LC 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 veneering 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 VM®LC, VITA VM®LC flow, VITA VM®LC Primer 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®LC, VITA VM®LC flow, VITA VM®LC Primer 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. Warning and precautions

- **When working with the product, wear suitable safety goggles/ face protection, gloves and safety clothing.**
- **Work under an extraction unit.**
- **Avoid contact with skin.**
- **In case of contact with eyes, rinse immediately with water and seek medical advice.**
- **In case of contact with skin, rinse immediately with copious of water.**
  Substances hazardous to water must not be allowed to enter the sewage system/to reach the environment.

- The restoration should be rinsed with water after each meal and cleaned mechanically at least once a day.

- Mechanical cleaning: hold the denture over a washbasin filled with water and clean from all sides.
- Use **a soft or medium-hard toothbrush or denture brush** and **a small quantity of abrasive toothpaste for cleaning.**
- Frequent consumption of coffee, tea, nicotine and in some cases, medication, may cause discoloration.
- In such cases, the restoration should be cleaned repeatedly.
- **It is strongly advised not to use cleaning tabs or cleaning solutions.**
- The active substances damage the material surfaces and cause discoloration and plaque deposits.

The following VITA VM LC products or accessories require hazard identification:		
VITAVM®LC MODELLING LIQUID (Contains triethylene glycol dimethacrylate, 2-dimethylaminoethyl methacrylate)	Causes skin irritation. Causes severe eye irritation. May cause respiratory irritation. May cause allergic skin reactions.	
VITAVM®LC SEPARATOR (contains cyclohexane, toluene, methyltriacetoxysilane)	Highly flammable liquid and vapor. Possible risk of harm to the unborn child. May cause damage to organs through prolonged or repeated exposure. May be fatal if swallowed and enters airways. Causes serious eye damage. Very toxic to aquatic life with long lasting effects Causes skin irritation. May cause drowsiness and dizziness.	    

VITAVM®LC CLEANER (Contains ethanol)	Highly flammable liquid and vapor. Causes severe eye irritation.	
VITAVM®LC OPAQUE LIQUID (contains methyl methacrylate, ethylene glycol dimethacrylate, 2-dimethylaminoethyl methacrylate)	Highly flammable liquid and vapor. Causes skin irritation. May cause allergic skin reactions. May cause respiratory irritation.	
VITAVM®LC OPAQUE PASTE VITAVM®LC GINGIVA OPAQUE PASTE (contains 2-dimethylaminoethyl methacrylate)	Causes skin irritation. Causes severe eye irritation. May cause allergic skin reactions. Harmful to aquatic life with long-lasting effects.	
VITAVM®LC PRE OPAQUE (contains 2-dimethylaminoethyl methacrylate)	Harmful to aquatic life with long-lasting effects May cause an allergic reaction.	
VITAVM®LC PAINT (contains 2-dimethylaminoethyl methacrylate, triethylene glycol dimethacrylate)	Causes skin irritation. Causes serious eye irritation. May cause an allergic reaction. Harmful to aquatic organisms with long-term adverse effects.	
VITAVM®LC flow (Contains triethylene glycol dimethacrylate, 2-dimethylaminoethyl methacrylate)	Causes skin irritation. Causes severe eye irritation. May cause allergic skin reactions. Harmful to aquatic life with long-lasting effects.	

VITA VM LC PRIMER I (Contains acetone, MDP, acetic acid)	Highly flammable liquid and vapour. Causes skin irritation. Causes severe eye irritation. May cause drowsiness or dizziness.	
VITA VM LC PRIMER II (Contains methyl methacrylate, UDMA, ethyl phenyl(2,4,6-trimethylbenzoyl)phosphinate)	Highly flammable liquid and vapor. Causes skin irritation. May cause allergic skin reactions. May cause respiratory irritation. Harmful to aquatic life with long-lasting effects.	

All these warnings and precautions can also be found in the corresponding instructions for use.