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

VITA AKZENT®LC

# Table of content



**Revision History**

| Version | Changes |
|---|---|
| 001 | Initial version |
| 002 | Annual Update |
| 003 | Annual Update |
| 004 | Annual Update |
| 005 | Annual Update |

## Identification of the device


| | |
|---|---|
| Device trade name | VITA AKZENT®LC |
| Manufacturer | VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen |
| Manufacturers SRN | DE-MF-000005906 |
| BASIC-UDI-DI | ++J017BC3PV (VITA AKZENT LC products); ++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 | 2021 |
| Notified Body including identification no. | DEKRA Certification GmbH, identification no.: 0124 |

## Indications, Intended Purpose and Target populations

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|---|---|
| Intended purpose | VITA AKZENT LC products are unfilled resin sealant and coating materials for dental treatments. |
| Indication | • Restorations made of hybrid ceramic (VITA ENAMIC) |

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|---|---|
| | • Restorations made of light-curing veneering material (e.g., VITA VM LC)<br>• Restorations made of CAD/CAM composites (e.g., VITA CAD-Temp)<br>• Prefabricated teeth (e.g., VITAPAN)<br>• Denture bases (e.g., VITA VIONIC BASE)<br>• Restorations and denture bases made of 3D printing acrylic polymers |
| Contraindication | • In patients with allergies or sensitivies to the ingredients<br>• Do not use on occlusal contact points of restorations<br>• Not approved for intraoral use |
| Intended user | Dental technician, Dentist, Professional User, Rx only |

# Device description

## a) Description of the medical device(s)

VITA AKZENT LC is a light-curing methacrylate-based stain/glaze system for extraoral surface characterization of dental restorations made of hybrid ceramic, resin veneering materials, CAD/CAM composites, prefabricated teeth, denture base resins and 3D printing acrylic polymers. It can also be used for internal characterization with the layering technique of veneering composites.

## b) Previous generations of the medical device(s)

There are no previous generations of the device manufactured by VITA.
VITA ENAMIC Stains, manufactured by Innovation MediTech, is the previous generation of the product. It is very similar in its composition, indication and application.

## 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 flow (VITA Zahnfabrik) | VITA AKZENT LC can be mixed with VITA VM LC flow at a maximum ratio of 1:10 |
| VITA ADIVA Microbrush (Harvard Dental International) | For application of VITA AKZENT LC GLAZE |
| VITA AKZENT LC CLEANER (VITA Zahnfabrik) | For cleaning the brushes after application |
| Brushes (VITA Zahnfabrik) | Brushes included in kit. Used for application of the stains/glaze |
| ceramic mixed palette (VITA Zahnfabrik) | ceramic mixed palette in which the stains are applied or mixed. |
| Polishing paste Zircopol (Feguramed) | Polishing of glazed surface after final polymerization |
| Soft goat hair brush (various manufacturers) | Polishing of glazed surface after final polymerization |
| Dry cotton buff (various manufacturers) | To achieve final shine of glazed surface |

| | |
|---|---|
| Polymerization devices/ lamps (various manufacurers) | For polymerization of VITA AKZENT LC, polymerization devices/ lamps that emit light in the wavelength range from 350 nm to 500 nm have to be used (Recommended devices are listed in the instructions for use longversion or in the working instruction |

## Possible therapeutic or diagnostic alternatives

| Diagnostic/therapeutic alternative with conditions of use | Possible benefit/advantage and possible risks/disadvantages as far as known |
|---|---|
| VITA AKZENT LC are characterization materials indicated for the staining 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 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 (2023) 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 droppinig*
- *DIN EN 62366:2021-08 Medical devices - Application 01 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 Biologische Beurteilung von Medizinprodukten - Teil 1: Anforderungen und allgemeine Grundsätze für die Beurteilung der biologischen Sicherheit im Rahmen eines Risikomanagementsystems*
- *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 10993-12:2021-08 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*
- *DIN EN ISO 10993-13:2024-04 Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices*
- *DIN EN ISO 10993-14:2024-04 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*
- *DIN EN ISO 10993-16:2024-04Biological evaluation of medical devices – Part 16: Toxicokinetic study design for degradation products and leachables*
- *DIN EN ISO 10993-17:2026-05 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents*
- *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 10993-23:2021-10 Biological evaluation of medical devices - Part 23: Test for irritation*
- *DIN EN ISO 10993-3:2024-04 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *DIN EN ISO 10993-4:2017-12 Biological evaluation of medical devices– Part 4: Selection of tests for interactions with blood*
- *DIN EN ISO 10993-5:2024-04 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- *DIN EN ISO 10993-6:2024-04 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 17665:2024-09 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices*
- *DIN EN ISO 18675:2023-04 Dentistry - Machinable ceramic blanks*
- *DIN EN ISO 20417:2022-03 Information to be supplied by the manufacturer of medical devices;*
- *DIN EN ISO 4180:2020-03 Packaging - Complete filled tranport packages- General rules for compilation of performance test schedules*
- *DIN EN ISO 7405:2025-12 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*
- *DIN EN ISO 6872:2024-12 Dentistry - Ceramic materials*
- *DIN EN ISO 9693:2020-02 Dentistry – Compatibility testing for metal-ceramic and ceramic-ceramic systems*
- *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 13485:2016-03 Medical devices — Quality management systems — Requirements for regulatory purposes*
- *ISO 14801:2016-11 Dentistry Implants - Dynamic loading test for endosseus dental implants*
- *ISO 14971:2019-12 Medical Devices - Application of risk management to medical devices*
- *ISO 15223-1:2021-07 Amd 1:2025-03 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*
- *ISO 15223-1:2021-07 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -by the manufacturer - Part 1: General requirements*
- *ISO 18675:2022-05 Dentistry - Machinable ceramic blanks*
- *ISO 20417:2021-12 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 tranport packages- General rules for compilation of performance test schedules*
- *ISO 7405:2025-06 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 24971:2020-06 Medical devices — Guidance on the application of ISO 14971*
- *Use of International Standard ISO 10993-1, "Biological Evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Guidance for Industry and Food and Druf Administration Staff. September 8, 2023*
- *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 on a Person responsible for Regulatory Compliance (PRRC)*
- *MDCG 2019-9 Summary of safety and clinical performance*
- *MDCG 2020:6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC*
- *MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD*
- *MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template - A guide for manufacturers and notified bodies*
- *MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies*
- *MDCG 2021-1 Rev.1 Guidance on harmonised administrative practices and alternative technical solutions 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 in accordance with Directives 90/385/EEC or 93/42/EEC*
- *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 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_rev4_en 2016-06 Guideline on Medical Devices*
- *Recommendation-NB-MED/2_5-2/Rec2_Reporting of design changes and changes of the quality system; 2.5.2 Conformity assessment procedures; Quality assurance.*

# 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 Veneering Polymers and Stains VITA VM CC, VITA VM LC, VITA AKZENT LC" 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 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 AKZENT®LC 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 AKZENT®LC 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 product, wear suitable safety goggles/ face protection and light respiratory protection.**

| **The following VITA AKZENT LC products or accessories require hazard identification:** | | |
|---|---|---|
| VITA AKZENT LC EFFECT STAINS / CHROMA STAINS / GLAZE | • Highly flammable liquid and vapor.<br>• Causes skin irritation.<br>• May cause allergic skin reactions.<br>• Causes serious eye damage.<br>• May cause respiratory irritation.<br>• Harmful to aquatic life with long-lasting effects<br>• Wear protective gloves/protective clothing/eye protection.<br>• Keep the container tightly closed.<br>• Protect from heat. No smoking. |  |
| VITA AKZENT LC CLEANER | • Highly flammable liquid and vapor.<br>• Causes severe eye irriation.<br>• Keep the container tightly closed.<br>• Protect from heat.<br>• Keep away from ignition sources. |  |

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