VITA Zahnfabrik
H. Rauter GmbH & Co. KG
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Germany
006/11.2026

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

VITA AKZENT® Plus

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Revision History

Version	Changes
004	**New clinical evaluation Yearly update**
005	**Yearly update**
006	**Formal Update on first page and updating standards**

Identification of the device



Device trade name	VITA AKZENT® Plus
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017BB3PS (VITA AKZENT Plus) ++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	VITA AKZENT PLUS: 2012
Notified Body including identification no.	DEKRA Certification GmbH, Identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA AKZENT PLUS products are material-kits for porcelain/ceramic restaurations for dental treatments.
Indication	VITA AKZENT PLUS: • for internal shade modification and external characterization Compatible with all dental ceramic materials: • CAD/CAM materials (e.g. VITABLOCS, VITA YZ SOLUTIONS) • All-ceramics (such as VITA LUMEX AC) • Metal ceramics (such as VITA VM 13) • Press ceramics (such as VITA PM 9) • Suitable for the firing temperatures from 750 °C to 950 °C • CTE independent
Contraindication	VITA AKZENT PLUS: None known.
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a) Description of the medical device(s)

VITA AKZENT® Plus is an assortment of stains for creating natural effects at the surface of the tooth. VITA AKZENT® Plus stains are designed for surface characterization -for example in the gingival area -as well as for reproducing natural discoloration effects such as decalcification marks and cracks in the enamel.

The stains offer a range of applications and are available as a powder/liquid, as a paste and as a spray.

They are suitable for use with all VITA Veneering Ceramics. The stains are also ideal for adding color characterizations to VITABLOCS®.

b) Previous generations of the medical device(s)

VITA Akzent Plus development was a harmonization of the VITA Shading paste, VITA Akzent Stains, and Glaze System. The chemical composition and clinical use is identical to the previous VITA Akzent and VITA Shading Paste only the naming is different. The difference is that VITA Shading Paste is now integrated in the Akzent Plus stain system with the name VITA AKZENT PLUS Shading Paste and the shade system is split in VITA AKZENT PLUS Effect Shades and VITA AKZENT PLUS Body Stains. They are the same raw material and pigments only some shades are adjusted

and the VITA AKZENT PLUS Body Stains are now available in the application as spray. Also see A2 Akzent vs Akzent Plus.

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.

Accessories for VITA AKZENT PLUS:

Name of accessory (manufacturer)	Short description
VITA AKZENT PLUS mixing plate	– 22 trough spaces for mixing all powder stains and glaze materials – one large hollow trough as a liquid reservoir, with small ring-shaped sponge
VITA AKZENT PLUS shade sample disc	– Disc with printed shade samples to assess the shade effect of the stains after firing – 14 EFFECT STAINS – 5 BODY STAINS
VITA AKZENT PLUS CHROMA STAINS Shade Guide	– Shade guide with printed shade samples to assess the stains after firing – 4 CHROMA STAINS classical A1-D4 – 5 CHROMA STAINS 3D-MASTER
VITABLOCS Mark II	Recommended substructure

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 PLUS is a characterization material indicated for the staining of dental restorations. It is 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 minimised.

Reference to harmonized standards and CS applied

Common specifications are not used for the product VITA AKZENT PLUS. 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 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 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 03:2026 Requirements and general principles for the evaluation of biological safety within a risk management process*
- *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 02:2026 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 05:2026 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents*
- *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 03:2026 Biological evaluation of medical devices - Part 23: Test for irritation*
- *DIN EN ISO 10993-3 11:2026 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 08:2026 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 transport packages - General rules for compilation of performance test schedules*
- *DIN EN ISO 7405 12:2025 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry*
- *ISO 10993-1 11:2025 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 transport packages- General rules for compilation of performance test schedules*

- *ISO 7405 06:2025 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 organization'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 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices*
- *MDCG 2023-7 Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61 4-6 MDR*
- *MEDDEV 2.7.1/rev4 06:2016 GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC*
- *Recommendation NB-MED/2.5.2/Rec2 Reporting of design changes and changes of the quality system*

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 product under evaluation (VITA AKZENT PLUS) has been lawfully placed on the market and put into service in accordance with Directive 93/42/EEC and the clinical evaluation of this product 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 June 2025/Rev. 06:

[…] *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 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 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 PLUS 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 PLUS it can be said that the clinical evaluation of the product is clearly states the clinical safety and performance. There is no doubt about the safety and reliability of the product. It 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

- **Extremely flammable aerosol**



Spray-on ceramic glaze material. For dental applications only. Not for intraoral use. Shake well before use. Pressurized container: do not puncture or burn. Protect from direct sunlight and temperatures above 50 C°. Do not pierce or burn even after use. Do not spray into flames or onto glowing objects. Keep away from ignition sources. - No smoking. Keep away from heat / sparks / open flame / hot surfaces. IMPORTANT: VITA AKZENT PLUS glaze sprays must not be used in combination with spray-on opaque materials.

- **In case of formation of dust, use an extraction system or wear a face mask.**



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