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

Sirona CEREC Blocs, VITABLOCS RealLife®, VITABLOCS® Mark II, VITABLOCS® TriLuxe forte

Table of content

Revision History

Version	Changes
001	**Initial version**
002	**New clinical evaluation; see chapter "Clinical Evaluation"**
003	**Yearly update**
004	**Yearly update**

Identification of the device

Device trade name	Sirona CEREC Blocs, VITABLOCS RealLife®, VITABLOCS® Mark II, VITABLOCS® TriLuxe forte
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017CC1PW (Blocs) ++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	VITABLOCS: 1990
	VITABLOCS Mark II: 1991
	VITABLOCS TriLuxe forte: 2007
	VITABLOCS RealLife: 2010
Notified Body including identification no.	DEKRA Certification GmbH, Identification no.: 0124

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Germany
005/06.2025

Indications, Intended Purpose and Target populations

Intended purpose	VITABLOCS products are ceramic materials for dental treatments.
Indication	**Overview of indications of fine-structure feldspar ceramic:**

Indication / Type of material	VITABLOCS Mark II	VITABLOCS TriLuxe forte	VITABLOCS RealLife
 Inlay	●	○	○
 Onlay	●	○	○
 Table top	●	○	○
 Veneer	○	●	●
 Endo-crown*	○	○	○
 Anterior crown	○	●	●
 Posterior crown	○	○	○
 Veneer structure for the VITA Rapid Layer Technology	●	●	–

● recommended ○ possible * molars only

Contraindication	**General** • in cases of inadequate oral hygiene • insufficient preparation results • insufficient hard tooth substance • insufficient space available **Hyperfunction** • Restorations made of VITABLOCS are contraindicated for patients diagnosed with excessive occlusal function, in particular those who grind and clench their teeth. The use of VITABLOCS restorations for devitalized teeth of patients with hyperfunctions is absolutely contraindicated. **Endo-crowns - premolars** • Due to the small adhesive surface and the small root diameters, endo-crowns for premolars are contraindicated. **Bridges** • Since VITABLOCS consist of a fine-structure feldspar ceramic with a limited strength of approx. 140 MPa, this material is not suitable for the fabrication of monolithic (mono-ceramic) bridges. **All-ceramic substructures** • VITABLOCS are not suitable for the fabrication of all-ceramic substructures. Accordingly, VITA LUMEX must only be used for individualizing and not for full veneers of copings made from these materials (see information on page 28).
Intended user	Dental technician, Dentist, Professional User, Rx only

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Device description

a) Description of the medical device(s)

All VITABLOCS are industrially manufactured, fine-structure feldspar ceramic blocks used to fabricate inlays, onlays, veneers and crowns with various CAD/CAM systems.

VITABLOCS MARK II is a homogeneously colored bloc.

VITABLOCS TriLuxe forte has four layers of different shade intensity. They have a more finely nuanced color transition from the enamel to the neck layer while the chroma in the lower dentine or neck area is increased. In conjunction with the cervically increasing fluorescence, this guarantees a convincingly natural shade effect even in the case of thin wall thicknesses.

VITABLOCS RealLife are especially developed for highly esthetic anterior restorations. The threedimensional block structure with dentine core and enamel coat imitates the curved shade transitions between dentine and incisal edge.

Accordingly, VITABLOCS RealLife restorations may have more cervical or incisal proportions in accordance with the natural shade nuances of the residual tooth substance.

CEREC® Blocs C und CEREC® Blocs C PC are the names for VITABLOCS in cooperation with our partner SIRONA.

b) Previous generations of the medical device(s)

VITABLOCS were firstly marked in 1990. VITABLOCS TriLuxe forte have been available in different shade intensity levels since 2007. VITABLOCS RealLife were introduced in 2010. VITABLOCS TriLuxe, TriLuxe forte and RealLife are produced from the proven Mark II ceramic.

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
VITAVM®9 ESTHETIC KIT for VITABLOCS®	Assortment containing a selection of VITA VM 9 materials, which are perfectly suitable for individualizing restorations made of VITABLOCS.
VITA AKZENT® Plus PASTE KIT	Assortment of 19 ready-to-use, fine-grained stain pastes for shade characterization of restorations made of VITABLOCS, particularly for use in dental practices.
VITA AKZENT® Plus POWDER KIT	Assortment of 19 ceramic stain powders for characterizing restorations made of VITABLOCS. The stains have good stability characteristics, as well as shade stability and can be mixed with one another.
VITA AKZENT® Plus SPRAY KIT	Assortment containing five BODY SPRAYS and one GLAZE SPRAY. Especially suited for staining large surfaces, particularly for monolithic restorations.
VITA AKZENT® Plus GLAZE SPRAY	Easy to apply, spray-on ceramic powder for simple and time-saving glazing of ceramic restorations. Ideal for glazing monolithic restorations made of VITABLOCS in the dental practice.
VITA FIRING PASTE	Ready-to-use, fire-resistant paste for the fabrication of individual firing trays. The material enables secure attachment of objects on the firing tray. The paste can be easily removed again after firing.
VITA Linearguide 3D-MASTER ®/ VITA Toothguide 3D-MASTER®	With the VITA Linearguide 3D-MASTER, you can determine the correct tooth shade quickly and precisely. The modern design and the linear arrangement enable quick determination of the suitable tooth shade. The VITA Linearguide 3D-MASTER is an alternative to the proven VITA Toothguide 3D-MASTER and features different (linear) arrangements of the shade sample teeth.
VITA Easyshade® V	The digital shade measurement device VITA Easyshade V, allows users to determine the shade of natural teeth, or to verify restorations in a matter of seconds, regardless of available lighting. The tooth shade measured is indicated in VITA classical A1-D4, VITA SYSTEM 3D-MASTER and in VITABLOCS shades. Seamless design, Bluetooth®, communication software for PC, smartphone and tablet, inductive charging and many new features guarantee maximum precision, quality and ease of use.

VITA Powder Scan Spray	Bottle containing 75 ml of blue, titanium dioxide-free spray-on pigment suspension with mint flavor for direct application (tooth surface) and for indirect use (plaster die/plaster model) for the opto-electronic impression of CAD/CAM restorations.
VITA ADIVA FULL-ADHESIVE LUTING SET	Assortment includes all materials for full-adhesive bonding of restorations fabricated using VITABLOCS.
VITA ADIVA F-CEM	Dual-curing, full-adhesive luting composite in four shades (A2 Universal, A3, White opaque and Translucent). Automix syringe cont. 5 ml, with material-saving T-mixers.
VITA ADIVA IA-CEM	Dual-curing full-adhesive, ultra-opaque bonding composite for severely discolored preparations, metal post and core structures, etc., in Automix syringe cont. 5 ml with material-saving T-mixers.
VITA ADIVA T-BOND SET	Dual-curing dentine/enamel bonding system.
VITA ADIVA TOOTH-ETCH	35% orthophosphoric acid gel for etching tooth substance, blue colored, good stability characteristics
VITA CERAMICS ETCH	Hydrofluoric acid gel, 5%, for etching silicate ceramics, red colored.
VITA ADIVA C-PRIME	Single-component silane bonding agent
VITA ADIVA OXY-PREVENT	VITA ADIVA OXY-PREVENT Neutral-colored glycerine gel to prevent the formation of an oxygen inhibition layer. It is also suitable for use as a try-in paste.
VITA Karat diamond polishing set	Assortment containing 5 g of diamond polishing paste, 20 diamond felt wheels (Ø 12 mm) and one nickel-plated mandrel.
VITABLOCS®-Box	Metal-reinforced box made of high-quality acrylic for storing up to 12 VITABLOCS bars.
Storage box	Storage box made of high-quality acrylic for storing up to 36 VITABLOCS bars.
VITA SMART.FIRE, VITA VACUMAT 6000 M or VITA V60 i-Line	A furnace, such as, is required for characterizing with stains and glaze material and for individualizing with VITA VM 9.

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
Analogous restorations made of zirconium dioxide-reinforced lithium silicate, lithium silicate, zirconium dioxide, hybrid ceramics, composite, gold casting or non-precious metal alloys can serve as therapeutic alternatives for restorations with VITABLOCS.	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 products Sirona CEREC Blocs, VITABLOCS RealLife®, VITABLOCS® Mark II, VITABLOCS® TriLuxe forte. 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 18675 04:2023 Dentistry - Machinable ceramic blanks*
- *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 18675 05:2022 Dentistry - Machinable ceramic blanks*
- *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 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*
- *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*

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 "VITABLOCS" at novineon CRO GmbH January 2023/Rev.03: "[...] On the basis of the documentation provided by VITA, we conclude that the potential risks of the VITABLOCS are acceptable residual risks for the patient and the user. The main risks 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 dental machinable ceramic blanks are well-documented in the published literature, thus being known to the qualified and trained medical professional user. When complying with all warnings and precautions, VITABLOCS 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 is pictured below and 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 Sirona CEREC Blocs, VITABLOCS RealLife®, VITABLOCS® Mark II, VITABLOCS® TriLuxe forte 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 Sirona CEREC Blocs, VITABLOCS RealLife®, VITABLOCS® Mark II, VITABLOCS® TriLuxe forte 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 work is in progress, wear suitable safety goggles/face protection, gloves and safety clothing. 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).