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

CEREC MTL Zirconia, VITA YZ® SOLUTIONS

Table of content

Revision History

Version	Changes
001	**Initial version**
002	**Transfer to new form**
003	**New form and merging of CEREC MTL Zirconia and YZ SOLUTIONS due to same Basic-UDI DI**
004	**Annual update**

Identification of the device

Device trade name	CEREC MTL Zirconia, VITA YZ® SOLUTIONS
Manufacturer	VITA Zahnfabrik H. Rauter GmbH & Co. KG Spitalgasse 3 D-79713 Bad Säckingen
Manufacturers SRN	DE-MF-000005906
BASIC-UDI-DI	++J017CC2PY (YZ Solution Ceramics), ++J017CE1Q4 (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 YZ SOLUTIONS: 2018
	CEREC MTL Zirconia: 2021
Notified Body including identification no.	DEKRA Certification GmbH, identification no.: 0124

Indications, Intended Purpose and Target populations

Intended purpose	VITA YZ SOLUTIONS and CEREC MTL Zirconia are ceramic materials for dental treatments.

Indication	VITA YZ SOLUTIONS: VITA YZ T: • fully anatomical crowns and bridges* with up to 14 units in the anterior and posterior tooth regions, • fully and partially veneered single teeth and bridge substructures* of up to 14 units in the anterior and posterior tooth regions, • single tooth restorations and bridges* with up to 14 units on directly screwed implant abutments in the anterior and posterior tooth regions, • primary telescopes, • inlays***, onlays***, veneers***, partial crowns***, occlusal veneers (Table Top)*** VITA YZ HT: • fully-anatomical crowns and up to 14-unit bridges* in the anterior and posterior tooth regions, • fully and partially veneered single-tooth and up to 14-unit bridge substructures* in the anterior and posterior tooth regions, • single tooth restorations and up to 14-unit bridges* on directly screwed implant abutments in the anterior and posterior tooth regions, • primary telescopes, • inlays***, onlays***, veneers***, partial crowns***, occlusal veneers (Table Top)*** VITA YZ ST: • fully-anatomical crowns and up to 14-unit** bridges* in the anterior and posterior tooth regions, • fully and partially veneered single-tooth and up to 14-unit bridge** substructures in the anterior and posterior tooth regions, • single tooth restorations and up to 14-unit** bridges* on directly screwed implant abutments in the anterior and posterior tooth regions, • inlays***, onlays***, veneers***, partial crowns***, occlusal veneers (Table Top)*** VITA YZ XT: • fully anatomical single tooth crowns and up to 3-unit bridges, • fully and partially veneered single-tooth crowns and up to 3-unit bridge superstructures in the anterior and posterior tooth region,

	• inlays***, onlays***, veneers***, partial crowns***, occlusal veneers (Table Top)*** *) Bridges and bridge superstructures with a maximum of two adjoining bridge pontics. **) VITA YZ ST is limited in Canada to bridge indications with a maximum of six units with a maximum of two adjoining bridge pontics. ***) For adhesive bonding only. CEREC MTL Zirconia: • fully anatomical anterior and posterior crowns • fully anatomical 3-unit anterior and posterior bridges • Onlays • Inlays • Veneers
Contraindication	VITA YZ SOLUTIONS for VITA YZ T, VITA YZ HT, VITA YZ ST and VITA YZ XT • in cases of more than two contiguous bridge units • in cases of two or more cantilever bridge units • in cases of parafunctions for veneered restorations, especially for "crunchers" and "pressers" • in cases of insufficient oral hygiene • in cases of insufficient preparation results • in cases of insufficient hard tooth substance • in cases of patients who have allergies or sensitivities to the contents provisional integration of veneered restorations • conventional or self-adhesive insertion of inlays, onlays, veneers, partial crowns and occlusal veneers (Table Top) also with VITA YZ XT • in cases of bridge restorations with more than three units • in cases of cantilever bridges • provisional integration CEREC MTL Zirconia: • more than one bridge pontics • more than one cantilever bridge unit • patients with parafunctions in particular for bruxism

	• insufficient oral hygiene • insufficient preparation results • insufficient hard tooth substance • patients who have known allergies or sensitivities to the chemical ingredients of the material • conventional or self-adhesive insertion of inlays, onlays, veneers
Intended user	Dental technician, Dentist, Professional User, Rx only

Device description

a) Description of the medical device(s)

VITA YZ SOLUTIONS includes zirconia blanks in four degrees of translucency with matched system components for reliable shade reproduction. VITA YZ blanks can be used for the production of fully/partially veneered reconstructions and monolithic bridge restorations in the anterior and posterior tooth regions. VITA YZ blanks come in many different versions: T (Translucent), HT (High Translucent), ST (Super Translucent), XT (Extra Translucent), White (uncolored), Color (monochrome, tooth-shaded), Multicolor (polychrome, tooth-shaded).

CEREC MTL Zirconia blocks for CEREC® are material comprised of zirconia ceramics for the fabrication of individually designed restorations using a CAD/CAM procedure. The aesthetic features of CEREC MTL Zirconia enable application as fully anatomical crowns and bridges. Indirect restorations are fabricated by milling CEREC MTL Zirconia blocks using a Dentsply Sirona CAD/CAM system. The CEREC MTL Zirconia blocks are provided in a partially sintered state, then milled enlarged by the CEREC CAD/CAM system. Restorations are individually processed to specification, and finally, densely sintered in the CEREC SpeedFire Sintering Furnace. The software determines the sintering program according to indication. Note that CAREC® software 5.1.3 with material pack or higher is required. CEREC MTL Zirconia blocks are available in blended shades, to match the VITA classical A-D shade guide tab CEREC MTL Zirconia blocks are available in 2 sizes: mono (20 mm) for most single-unit crowns and medi (39 mm) for most 3-unit bridges.

b) Previous generations of the medical device(s)

VITA In-Ceram YZ was the initial generation of zirconia material at VITA.

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 YZ SOLUTIONS:

Name of accessory (manufacturer)	Short description
VITA Easyshade V, VITA Linearguide 3D-MASTER	For digital shade determination, use VITA Easyshade V, and for traditional shade determination, the VITA Linearguide 3D-MASTER, for example.
VITA YZ COLORING LIQUID or VITA YZ SHADE LIQUIDS or EFFECT LIQUIDs	For manual coloring of the milling results, use the VITA YZ COLORING LIQUID (T) or the respective VITA YZ SHADE LIQUIDS (HT/ST/XT) and EFFECT LIQUIDS.
VITA ZYRCOMAT 6000 MS/6100 MS	Sinter the restoration made of VITA YZ with the VITA ZYRCOMAT 6000 MS/6100 MS sintering furnace.
VITA VM 9	For particularly esthetic results, use the VITA veneering ceramic VITA VM 9, which is adapted to zirconia.
VITA AKZENT Plus	Use the VITA AKZENT Plus stains/glazing materials for the characterization of VITA YZ.
VITA VACUMAT 6000 M	Fire the restoration made from VITA YZ with the VITA VACUMAT 6000 M firing furnace.
VITA SUPRINITY Polishing Set	Use the recommended polishing set for VITA YZ
VITA ADIVA LUTING SOLUTIONS	Secure the zirconia restoration with full adhesive or self-adhesive using VITA ADIVA LUTING SOLUTIONS.
YZ Brush	metal-free brush (e.g., YZ BRUSH) for manual coloring using brush technique
Pentel brand brushes	Can alternatively be used for metal-free brushes.
VITA CAD-Waxx	Full veneering using press-to technique; The wax-up can be done using CAD/CAM technology with VITA CAD-Waxx or manually with modeling wax (directly on the substructure).

Accessories for CEREC MTL Zirconia:

Name of accessory (manufacturer)	Short description
Calibra® Universal (Dentsply Sirona)	For final cementation of the restoration
Calibra® Bio Cement (Dentsply Sirona)	For final cementation of the restoration
CEREC SpeedPaste (Dentsply Sirona)	Used for fixation of the restoration on the firing pin
Glazing Support Single Unit +A	For placing one restoration in the firing unit
Glazing Support Multi Unit	For placing multiple restorations in the firing unit
Dentsply Sirona Universal Spray Glaze Fluo (Dentsply Sirona)	For glazing of the restauration in order to provide fluorescence
Dentsply Sirona Universal Spray Glaze (Dentsply Sirona)	For glazing of the restauration
DS Universal Glaze (Dentsply Sirona)	For glazing of the restauration
DS Universal Glaze Liquid (Dentsply Sirona)	For glazing of the restauration
Burs for CEREC Primemill and Burs for CEREC MC XL, CEREC MC X	For milling the restauration in the CEREC Primemill and CEREC MC XL, CEREC MC X
Sandblasting corundum (Aluminiumoxide), max. 50µm	Used for sandblasting the restoration prior to cementation

Possible therapeutic or diagnostic alternatives

Diagnostic/therapeutic alternative with conditions of use	Possible benefit/advantage and possible risks/disadvantages as far as known
Therapeutic alternatives of zirconia restorations can be; zirconia reinforced lithium silicate/ZLS, (CAD/CAM or press), in the case of press ceramics, three-unit bridges up to the second premolar, in the case of CAD/CAM restoration only single-tooth restoration. Hybrid ceramics, composites and feldspar ceramics can be alternatives in the case of single-tooth restorations, gold casting and non-precious alloys can also be used as alternatives beyond this.	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 product VITA YZ SOLUTIONS and CEREC MTL Zirconia. The following standards are applied for these products at VITA:

- *MEDDEV 2_7_1_rev4_en 06:2016*
- *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*
- *DIN EN 1641 10:2009 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 08:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (*
- *DIN EN ISO 10993-18 03:2021 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 10993-3 02:2015 Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- *DIN EN ISO 10993-4 12: 2017 Biological evaluation of medical devices– Part 4: Selection of tests for interactions with blood*
- *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 01:2019 Dentistry – Ceramic materials*
- *DIN EN ISO 7405 03:2019 Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
- *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 2206 04:1987 Packaging - Complete filled transport packages-Identification of parts when testing*
- *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 application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021*
- *MDCG 2022-4 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*

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 YZ SOLUTIONS VITA Zahnfabrik H. Rauter GmbH & Co. KG" at novineon CRO GmbH
May 2021/Rev.03: "[…] On the basis of the documentation provided by VITA, we conclude that the potential risks of the VITA YZ SOLUTIONS are acceptable residual risks for the patient and the user. The main risks, chipping or fracture of the dental restorations, 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 yttrium-stabilized zirconia products are well-documented in the published literature, thus bein known to dental physicians or adequately trained technicians. When complying with all warnings and precautions, VITA YZ SOLUTIONS 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 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 CEREC MTL Zirconia, VITA YZ® SOLUTIONS 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 CEREC MTL Zirconia, VITA YZ® SOLUTIONS 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

- **While work is in progress, wear suitable safety goggles / face protection.**
- **Only perform work under an extraction unit.**
- **Wear protective gloves.**

In case of working with VITA YZ HT SHADE LIQUID, VITA YZ ST SHADE LIQUID, VITA XT LIQUID, VITA YZ EFFECT LIQUID:

- Causes severe skin burns and eye damage.

- May cause respiratory irritation.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- Carefully wash hands, lower arms and face after use.
- Use only in the open air or in well-ventilated spaces.
- Wear protective gloves/protective clothing/eye and face protection.
- Wash contaminated clothing before wearing again.
- Dispose of contents/container in accordance with local/regional/ national/international regulations.

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