

IZJAVA EU O SKLADNOSTI EU DECLARATION OF CONFORMITY

Podjetje/ Company:

INTERDENT[®] d.o.o.

Naslov/ Address:

Opekarniška cesta 26, SI - 3000 CELJE

SRN:

SI-MF-000004584

Izjavljamo, da smo kot proizvajalec izključno odgovorni za izdajo izjave EU o skladnosti. /
We declare, that as a manufacturer, we are solely responsible for issuing the EU declaration of conformity.

Sledeči proizvodi, razvrščeni v razred IIa (pravilo 8) po prilogi VIII MDR,
Following Class IIa Products (rule 8) according to Annex VIII of the MDR,

GENERIČNO IME / GENERIC NAME	CAD/CAM DISKI Zr / CAD/CAM DISCS Zr
TRGOVSKO IME / TRADE NAME	CC DISK Zr CC DISK Zr HT CC DISK Zr HT MULTILAYER CC DISK Zr SMILE MULTILAYER
GMDN	16187
EMDN	Q010699
OSNOVNI UDI-DI / BASIC UDI-DI	++D058CCDISKZR2AGC

ustrezajo splošnim zahtevam glede varnosti in učinkovitosti Uredbe o medicinskih pripomočkih (EU) 2017/745 (MDR).
comply with general safety and performance requirements of the Medical Devices Regulation (EU) 2017/745 (MDR).

Postopek ugotavljanja skladnosti: Dodatek IX, Poglavje I in III Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 25.11.2025, številka registracije: HZ 1076832-1, veljavnost certifikata: 09.05.2028
Conformity assessment procedure: Annex IX, Chapter I and III of Medical Devices Regulation (EU) 2017/745, date of issue: 25.11.2025, registration No: HZ 1076832-1, certificate validity: 09.05.2028

Priglašeni organ za ugotavljanje skladnosti / *Notified body:*

TÜV Rheinland LGA Products GmbH, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **0197**

HARMONIZIRANI IN OSTALI STANDARDI / *HARMONISED AND OTHER STANDARDS:*

EN ISO 13485:2016+A11:2021 Medicinski pripomočki – Sistem vodenja kakovosti – Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*

EN ISO 14971:2019 / A11:2021 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*

CEN ISO/TR 24971:2020 Medicinski pripomočki - Navodilo za uporabo ISO 14971 / *Medical devices – Guidance on the application of ISO 14971*

EN ISO 15223-1:2021/A1:2025 Medicinski pripomočki – Simboli za označevanje medicinskih pripomočkov - 1. Del: Splošne zahteve / Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

EN ISO 10993-1:2026 Biološko ovrednotenje medicinskih pripomočkov - 1. del: Zahteve in splošna načela za oceno biološke varnosti znotraj procesa obvladovanja tveganja / *Biological Evaluation of Medical Devices- Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

EN ISO 10993-3:2014 Biološko vrednotenje medicinskih pripomočkov – 3. del: Preskusi za genotoksičnost, rakotvornost in reproduktivno toksičnost / Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity

EN ISO 10993-5:2009/A11:2025 Biološko vrednotenje medicinskih pripomočkov – 5. del: Preskusi zaugotavljanje citotoksičnosti in vitro / Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity

EN ISO 10993-6:2016 Biološko vrednotenje medicinskih pripomočkov – 6. del: Preskusi za lokalne učinke po vstavitvi vsadkov. / *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

EN ISO 10993-9:2021 Biološko ovrednotenje medicinskih pripomočkov - 9. del: Okvirni sistem za prepoznavanje in ugotavljanje količine morebitnih razgradnih produktov / *Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products*

EN ISO 10993-10:2023 Biološko vrednotenje medicinskih pripomočkov – 10. del: Preskusi za draženje in preobčutljivost kože. / *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*

EN ISO 10993-11:2018 Biološko vrednotenje medicinskih pripomočkov – 11. del: Preskusi za sistemsko toksičnost / *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*

EN ISO 10993-12:2021/A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 12. del: Priprava vzorcev in referenčni materiali / *Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*

EN ISO 10993-14:2009 Biološko ovrednotenje medicinskih pripomočkov - 14. del: Prepoznavanje in ugotavljanje količine razgradnih produktov iz keramike / *Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics*

EN ISO 10993-17:2023 /A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 17. del: Postavitev dopustnih mej za izlužene snovi / *Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*

EN ISO 10993-18:2020/A1:2023 Biološko vrednotenje medicinskih pripomočkov – 18. del: Kemijska opredelitev materialov / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*

EN ISO 7405:2025 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu / *Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*

EN 62366-1:2015/A1:2020 Medicinski pripomočki – Uporaba inženiringa uporabnosti medicinskih pripomočkov/ *Medical devices – Application of usability engineering to medical devices*

EN 1641:2009 Zobozdravstvo. Medicinski pripomočki za zobozdravstvo. Materiali / *Dentistry. Medical devices for dentistry. Materials.*

EN ISO 6872:2015/A1:2018 Zobozdravstvo - Keramični materiali / *Dentistry – Ceramic materials*

CEN ISO/TR 20416:2020 Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet / *Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet*

EN ISO 20417:2021 Informacije proizvajalca za medicinske pripomočke / *Information supplied by the manufacturer of medical devices*

EN ISO 9693:2019 Zobozdravstvo – preskušanje združljivosti – 1. Del: Kovinsko-keramični sistemi / *Dentistry – compatibility testing – Part 1: Metal-ceramic systems*

ISO/TS 10993-19:2020 Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials

EN ISO 10993-23:2021/A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja / *Biological evaluation of medical devices – Part 23: Tests for irritation*

ISO/TS 21726:2019 Biološko vrednotenje medicinskih pripomočkov – Uporaba praga toksikološke zaskrbljenosti (TTC) za oceno biokompatibilnosti sestavin medicinskih pripomočkov / *Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents*

EN ISO 9001:2015/A1:2024 Sistem vodenja kakovosti – zahteve / *Quality management system – requirements*

CR 13695-1:2000 Embalaža - Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži ter njihov izpust v okolje - 1. del: Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži / *Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging*

EN ISO 4180:2019 Embalaža - Celovita, napolnjena transportna embalaža - Splošna pravila za pripravo programov preskušanja primernosti za uporabo / *Packaging – Complete, filled transport packages – General rules for the compilation of performance test schedules*

ANSI/HIBC 2.6 standard 2016: Standard označevanja dobaviteljev zdravstvene industrije za varnost pacientov in edinstveno identifikacijo naprave (UDI) / *The health industry supplier labeling standard for patient safety & unique device identification (UDI)*

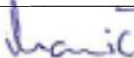
Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka ali na veljavnost certifikata priglašene organa. / *The validity of declaration of conformity is linked to a change in medical device or on validity of certificate issued by notified body.*

Celje, 10.04.2026

Place, Date

Anja Mavrič, B.Sc.

Responsible person for regulatory compliance
(MDR, Article 15 (3): (b) & (c))



Signature:

Verzija / Version: MDR 1

ANNEX TO DECLARATION OF CONFORMITY VERSION MDR 1 – ALL REF COVERED:

REF	DESCRIPTION (COLOUR, THICKNESS)	UDI-DI
1950	CC DISK Zr, 10 mm	+D0580000000019500
1951	CC DISK Zr, 12 mm	+D0580000000019510
1952	CC DISK Zr, 14 mm	+D0580000000019520
1953	CC DISK Zr, 16mm	+D0580000000019530
1954	CC DISK Zr, 18mm	+D0580000000019540
1955	CC DISK Zr, 20mm	+D0580000000019550
1956	CC DISK Zr, 22mm	+D0580000000019560
1957	CC DISK Zr, 25mm	+D0580000000019570
1951HT	CC DISK Zr HT, 12mm	+D0580000001950HT0
1951HTA1	CC DISK Zr HT A1, 12mm	+D058000001950HTA10
1951HTA2	CC DISK Zr HT A2, 12mm	+D0580000001951A30
1951HTA3	CC DISK Zr HT A3, 12mm	+D0580000001951HT0
1951HTA35	CC DISK Zr HT A3.5, 12mm	+D058000001951HTA10
1951HTA4	CC DISK Zr HT A4, 12mm	+D058000001951HTA20
1951HTB1	CC DISK Zr HT B1, 12mm	+D058000001951HTA30
1951HTB2	CC DISK Zr HT B2, 12mm	+D058000001951HTB20
1952HT	CC DISK Zr HT, 14mm	+D0580000001952HT0
1952HTA1	CC DISK Zr HT A1, 14mm	+D058000001952HTA10
1952HTA2	CC DISK Zr HT A2, 14mm	+D058000001952HTA20
1952HTA3	CC DISK Zr HT A3, 14mm	+D058000001952HTA30
1952HTA35	CC DISK Zr HT A3.5, 14mm	+D05800001952HTA350
1952HTA4	CC DISK Zr HT A4, 14mm	+D058000001952HTA40
1952HTB1	CC DISK Zr HT B1, 14 mm	+D058000001952HTB10
1952HTB2	CC DISK Zr HT B2, 14mm	+D058000001952HTB20
1952HTB3	CC DISK Zr HT B3, 14 mm	+D058000001952HTB30
1952HTB4	CC DISK Zr HT B4, 14 mm	+D058000001952HTB40
1952HTC3	CC DISK Zr HT C3, 14 mm	+D058000001952HTC30
1952HTC4	CC DISK Zr HT C4, 14 mm	+D058000001952HTC40
1952HTD2	CC DISK Zr HT D2, 14mm	+D058000001952HTD20
1952HTD4	CC DISK Zr HT D4, 14 mm	+D058000001952HTD40
1953A3	CC DISK Zr A3, 16 mm	+D0580000001953A30
1953HT	CC DISK Zr HT, 16 mm	+D0580000001953HT0
1953HTA1	CC DISK Zr HT A1, 16 mm	+D058000001953HTA10
1953HTA2	CC DISK Zr HT A2, 16 mm	+D058000001953HTA20
1953HTA3	CC DISK Zr HT A3, 16 mm	+D058000001953HTA30
1953HTB1	CC DISK Zr HT B1, 16 mm	+D058000001953HTB10
1953HTC2	CC DISK Zr HT C2, 16 mm	+D058000001953HTC20
1954A3	CC DISK Zr A3, 18 mm	+D0580000001954A30
1954HT	CC DISK Zr HT, 18 mm	+D0580000001954HT0
1954HTA1	CC DISK Zr HT A1, 18 mm	+D058000001954HTA10
1954HTA2	CC DISK Zr HT A2, 18 mm	+D058000001954HTA20
1954HTA3	CC DISK Zr HT A3, 18 mm	+D058000001954HTA30
1954HTA35	CC DISK Zr HT A3.5, 18 mm	+D05800001954HTA350

1954HTA4	CC DISK Zr HT A4, 18 mm	+D058000001954HTA40
1954HTB1	CC DISK Zr HT B1, 18 mm	+D058000001954HTB10
1954HTB2	CC DISK Zr HT B2, 98,5x18 mm	+D058000001954HTB20
1954HTB3	CC DISK Zr HT B3, 18 mm	+D058000001954HTB30
1954HTB4	CC DISK Zr HT B4, 18 mm	+D058000001954HTB40
1954HTC3	CC DISK Zr HT C3, 18 mm	+D058000001954HTC30
1954HTC4	CC DISK Zr HT C4, 18 mm	+D058000001954HTC40
1954HTD2	CC DISK Zr HT D2, 18 mm	+D058000001954HTD20
1954HTD4	CC DISK Zr HT D4, 18 mm	+D058000001954HTD40
1955A2	CC DISK Zr A2, 20 mm	+D05800000001955A20
1955A3	CC DISK Zr A3, 20 mm	+D05800000001955A30
1955HT	CC DISK Zr HT, 20 mm	+D05800000001955HT0
1955HTA1	CC DISK Zr HT A1, 20 mm	+D058000001955HTA10
1955HTA2	CC DISK Zr HT A2, 20 mm	+D058000001955HTA20
1955HTA3	CC DISK Zr HT A3, 20 mm	+D058000001955HTA30
1955HTB1	CC DISK Zr HT B1, 20 mm	+D058000001955HTB10
1955HTB2	CC DISK Zr HT B2, 20 mm	+D058000001955HTB20
1955HTD2	CC DISK Zr HT D2, 20 mm	+D058000001955HTD20
1956HT	CC DISK Zr HT, 22 mm	+D05800000001956HT0
1957A2	CC DISK Zr A2, 25 mm	+D05800000001957A20
1957A3	CC DISK Zr A3, 25 mm	+D05800000001957A30
1957HT	CC DISK Zr HT, 25 mm	+D05800000001957HT0
1957HTA1	CC DISK Zr HT A1, 25 mm	+D058000001957HTA10
1957HTA2	CC DISK Zr HT A2, 25 mm	+D058000001957HTA20
1957HTA3	CC DISK Zr HT A3, 25 mm	+D058000001957HTA30
1957HTB2	CC DISK Zr HT B2, 25 mm	+D058000001957HTB20
1957HTD2	CC DISK Zr HT D2, 25 mm	+D058000001957HTD20
1952MLHTA1	CC DISK Zr HT MULTILAYER A1, 14 mm	+D0580001952MLHTA10
1952MLHTA2	CC DISK Zr HT MULTILAYER A2, 14 mm	+D0580001952MLHTA20
1952MLHTA3	CC DISK Zr HT MULTILAYER A3, 14 mm	+D0580001952MLHTA30
1952MLHTA35	CC DISK Zr HT MULTILAYER A3.5, 14 mm	+D058001952MLHTA350
1952MLHTA4	CC DISK Zr HT MULTILAYER A4, 14 mm	+D0580001952MLHTA40
1952MLHTB1	CC DISK Zr HT MULTILAYER B1, 14 mm	+D0580001952MLHTB10
1952MLHTB2	CC DISK Zr HT MULTILAYER B2, 14 mm	+D0580001952MLHTB20
1952MLHTB3	CC DISK Zr HT MULTILAYER B3, 14 mm	+D0580001952MLHTB30
1952MLHTBL1	CC DISK Zr HT MULTILAYER BL1, 14 mm	+D058001952MLHTBL10
1952MLHTBL2	CC DISK Zr HT MULTILAYER BL2, 14 mm	+D058001952MLHTBL20
1952MLHTBL3	CC DISK Zr HT MULTILAYER BL3, 14 mm	+D058001952MLHTBL30
1952MLHTC1	CC DISK Zr HT MULTILAYER C1, 14 mm	+D0580001952MLHTC10
1952MLHTC2	CC DISK Zr HT MULTILAYER C2, 14 mm	+D0580001952MLHTC20
1952MLHTC3	CC DISK Zr HT MULTILAYER C3, 14 mm	+D0580001952MLHTC30
1952MLHTD2	CC DISK Zr HT MULTILAYER D2, 14 mm	+D0580001952MLHTD20
1952MLHTD3	CC DISK Zr HT MULTILAYER D3, 14 mm	+D0580001952MLHTD30
1952SMLA1	CC DISK Zr SMILE MULTILAYER A1, 14 mm	+D05800001952SMLA10
1952SMLA2	CC DISK Zr SMILE MULTILAYER A2, 14 mm	+D05800001952SMLA20

1952SMLA3	CC DISK Zr SMILE MULTILAYER A3, 14 mm	+D05800001952SMLA30
1952SMLA35	CC DISK Zr SMILE MULTILAYER A3.5, 14 mm	+D05800001952SMLA350
1952SMLB1	CC DISK Zr SMILE MULTILAYER B1, 14 mm	+D05800001952SMLB10
1952SMLB2	CC DISK Zr SMILE MULTILAYER B2, 14 mm	+D05800001952SMLB20
1952SMLB3	CC DISK Zr SMILE MULTILAYER B3, 14 mm	+D05800001952SMLB30
1952SMLC1	CC DISK Zr SMILE MULTILAYER C1, 14 mm	+D05800001952SMLC10
1952SMLC2	CC DISK Zr SMILE MULTILAYER C2, 14 mm	+D05800001952SMLC20
1952SMLD2	CC DISK Zr SMILE MULTILAYER D2, 14 mm	+D05800001952SMLD20
1952SMLD3	CC DISK Zr SMILE MULTILAYER D3, 14 mm	+D05800001952SMLD30
1954MLHTA1	CC DISK Zr HT MULTILAYER A1, 18 mm	+D0580001954MLHTA10
1954MLHTA2	CC DISK Zr HT MULTILAYER A2, 18 mm	+D0580001954MLHTA20
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1954MLHTA35	CC DISK Zr HT MULTILAYER A3.5, 18 mm	+D058001954MLHTA350
1954MLHTA4	CC DISK Zr HT MULTILAYER A4, 18 mm	+D0580001954MLHTA40
1954MLHTB1	CC DISK Zr HT MULTILAYER B1, 18 mm	+D0580001954MLHTB10
1954MLHTB2	CC DISK Zr HT MULTILAYER B2, 18 mm	+D0580001954MLHTB20
1954MLHTB3	CC DISK Zr HT MULTILAYER B3, 18 mm	+D0580001954MLHTB30
1954MLHTBL1	CC DISK Zr HT MULTILAYER BL1, 18 mm	+D058001954MLHTBL10
1954MLHTBL2	CC DISK Zr HT MULTILAYER BL2, 18 mm	+D058001954MLHTBL20
1954MLHTBL3	CC DISK Zr HT MULTILAYER BL3, 18 mm	+D058001954MLHTBL30
1954MLHTC1	CC DISK Zr HT MULTILAYER C1, 18 mm	+D0580001954MLHTC10
1954MLHTC2	CC DISK Zr HT MULTILAYER C2, 18 mm	+D0580001954MLHTC20
1954MLHTC3	CC DISK Zr HT MULTILAYER C3, 18 mm	+D0580001954MLHTC30
1954MLHTD2	CC DISK Zr HT MULTILAYER D2, 18 mm	+D0580001954MLHTD20
1954MLHTD3	CC DISK Zr HT MULTILAYER D3, 18 mm	+D0580001954MLHTD30
1954SMLA1	CC DISK Zr SMILE MULTILAYER A1, 18 mm	+D05800001954SMLA10
1954SMLA2	CC DISK Zr SMILE MULTILAYER A2, 18 mm	+D05800001954SMLA20
1954SMLA3	CC DISK Zr SMILE MULTILAYER A3, 18 mm	+D05800001954SMLA30
1954SMLA35	CC DISK Zr SMILE MULTILAYER A3.5, 18 mm	+D0580001954SMLA350
1954SMLB1	CC DISK Zr SMILE MULTILAYER B1, 18 mm	+D05800001954SMLB10
1954SMLB2	CC DISK Zr SMILE MULTILAYER B2, 18 mm	+D05800001954SMLB20
1954SMLB3	CC DISK Zr SMILE MULTILAYER B3, 18 mm	+D05800001954SMLB30
1954SMLC1	CC DISK Zr SMILE MULTILAYER C1, 18 mm	+D05800001954SMLC10
1954SMLC2	CC DISK Zr SMILE MULTILAYER C2, 18 mm	+D05800001954SMLC20
1954SMLD2	CC DISK Zr SMILE MULTILAYER D2, 18 mm	+D05800001954SMLD20
1954SMLD3	CC DISK Zr SMILE MULTILAYER D3, 18 mm	+D05800001954SMLD30
1956MLHTA1	CC DISK Zr HT MULTILAYER A1, 22 mm	+D0580001956MLHTA10
1956MLHTA2	CC DISK Zr HT MULTILAYER A2, 22 mm	+D0580001956MLHTA20
1956MLHTA3	CC DISK Zr HT MULTILAYER A3, 22 mm	+D0580001956MLHTA30
1956MLHTA35	CC DISK Zr HT MULTILAYER A3.5, 22 mm	+D058001956MLHTA350
1956MLHTB1	CC DISK Zr HT MULTILAYER B1, 22 mm	+D0580001956MLHTB10
1956MLHTB2	CC DISK Zr HT MULTILAYER B2, 22 mm	+D0580001956MLHTB20
1956MLHTB3	CC DISK Zr HT MULTILAYER B3, 22 mm	+D0580001956MLHTB30
1956MLHTBL1	CC DISK Zr HT MULTILAYER BL1, 22 mm	+D058001956MLHTBL10
1956MLHTBL2	CC DISK Zr HT MULTILAYER BL2, 22 mm	+D058001956MLHTBL20
1956MLHTBL3	CC DISK Zr HT MULTILAYER BL3, 22 mm	+D058001956MLHTBL30

1956MLHTC1	CC DISK Zr HT MULTILAYER C1, 22 mm	+D0580001956MLHTC10
1956MLHTC2	CC DISK Zr HT MULTILAYER C2, 22 mm	+D0580001956MLHTC20
1956MLHTD2	CC DISK Zr HT MULTILAYER D2, 22 mm	+D0580001956MLHTD20
1956MLHTD3	CC DISK Zr HT MULTILAYER D3, 22 mm	+D0580001956MLHTD30
1956SMLA1	CC DISK Zr SMILE MULTILAYER A1, 22 mm	+D05800001956SMLA10
1956SMLA2	CC DISK Zr SMILE MULTILAYER A2, 22 mm	+D05800001956SMLA20
1956SMLA3	CC DISK Zr SMILE MULTILAYER A3, 22 mm	+D05800001956SMLA30
1956SMLA35	CC DISK Zr SMILE MULTILAYER A3.5, 22 mm	+D05800001956SMLA350
1956SMLB1	CC DISK Zr SMILE MULTILAYER B1, 22 mm	+D05800001956SMLB10
1956SMLB2	CC DISK Zr SMILE MULTILAYER B2, 22 mm	+D05800001956SMLB20
1956SMLB3	CC DISK Zr SMILE MULTILAYER B3, 22 mm	+D05800001956SMLB30
1956SMLC1	CC DISK Zr SMILE MULTILAYER C1, 22 mm	+D05800001956SMLC10
1956SMLC2	CC DISK Zr SMILE MULTILAYER C2, 22 mm	+D05800001956SMLC20
1956SMLD2	CC DISK Zr SMILE MULTILAYER D2, 22 mm	+D05800001956SMLD20
1956SMLD3	CC DISK Zr SMILE MULTILAYER D3, 22 mm	+D05800001956SMLD30