INTERDENT® d.o.o.
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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 CoCr / *CAD/CAM DISCS CoCr***
TRGOVSKO IME / *TRADE NAME*	**CC DISK NF CoCr, CC DISK EASY CoCr, CC DISK WW CoCr**
GMDN	62817
EMDN	Q010601
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058CCDISKCOCRTI2AHK

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 Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 10.05.2023, številka registracije: HZ1076832-1, veljavnost certifikata: 09.05.2028 *Conformity assessment procedure: Annex IX, Chapter I of Medical Devices Regulation (EU) 2017/745, date of issue:* 10.05.2023, *registration No:* HZ1076832-1, *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*
EN ISO 15223-1:2021 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*

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EN ISO 10993-1:2020 Biološko vrednotenje medicinskih pripomočkov – 1. del: Ocena in preskusi znotraj ocene tveganja / *Biological evaluation of medical devices - Part 1: Evaluation and testing 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 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 10993-6:2009 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 10993-10:2013 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 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 10993-15:2009 Biološko vrednotenje medicinskih pripomočkov – 15. del: Identifikacija in kvantifikacija proizvodov razgradnje kovin in zlitin / *Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys*
EN ISO 10993-17:2009 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 Biološko vrednotenje medicinskih pripomočkov – 18. del: Kemijska opredelitev materialov / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*
EN ISO 7405:2018 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.*
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 22674:2022 Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja. / *Metallic materials for fixed and removable restorations and appliances*
EN ISO 9693:2019 Zobozdravstvo – preskušanje združljivosti – 1. Del: Kovinsko-keramični sistemi / *Dentistry – compatibility testing – Part 1: Metal-ceramic systems*
EN ISO 9333:2022 Zobozdravstvo – materiali za spajkanje / *Dentistry – Brazing materials*
EN ISO 10271:2020 Zobozdravstvc – Preskusne metode ugotavljanja korozije za kovinske materiale / *Dentistry – Corrosion test methods for metallic materials*
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 Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja / *Biological evaluation of medical devices – Part 23: Tests for irritation*

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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 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 priglašenega 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, 11.05.2023 — **Place, Date**

Anja Mavrič, B.Sc. — **Responsible person for technical files**

Signature:

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Verzija / *Version*: MDR 1

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

PRODUCT NAME	CATALOGUE NUMBER
CC DISK NF CoCr 8 mm	1900
CC DISK NF CoCr 10 mm	1901
CC DISK NF CoCr 12 mm	1902
CC DISK NF CoCr 13,5 mm	1903
CC DISK NF CoCr 15 mm	1904
CC DISK NF CoCr 18 mm	1905
CC DISK NF CoCr 22 mm	1906
CC DISK NF CoCr 25 mm	1907
CC DISK EASY CoCr 10 mm	1931
CC DISK EASY CoCr 12 mm	1932
CC DISK EASY CoCr 13,5 mm	1933
CC DISK EASY CoCr 15 mm	1928
CC DISK EASY CoCr 18 mm	1929
CC DISK EASY CoCr 22 mm	1948
CC DISK EASY CoCr 25 mm	1949
CC DISK WW CoCr 10 mm	1991
CC DISK WW CoCr 12 mm	1992
CC DISK WW CoCr 13,5 mm	1993
CC DISK WW CoCr 15 mm	1994
CC DISK WW CoCr 18 mm	1995
CC DISK WW CoCr 22 mm	1996
CC DISK WW CoCr 25 mm	1997