

IZJAVA O SKLADNOSTI DECLARATION OF CONFORMITY

Podjetje/Company: **INTERDENT® d.o.o.**
Naslov/Address: **Opekarniška cesta 26, SI - 3000 CELJE**

Na lastno odgovornost izjavljamo, da sledeči proizvodi, razreda IIa (pravilo 8)
We herewith declare on our sole responsibility that the following Class IIa Products (rule 8)

GENERICNO 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
UMDNS / GMDN	62817

ustrezajo bistvenim zahtevam Direktive o medicinskih pripomočkih 93/42/EGS.
comply with essential requirements of the Medical Devices Directive 93/42 EEC.

Postopek ugotavljanja skladnosti: Dodatek II (brez točke 4) Direktive o medicinskih pripomočkih 93/42/EGS, datum izdaje: 19. 05. 2021, številka registracije: HD 1076832-1, veljavnost certifikata: 26. 05. 2024

Conformity assessment procedure: Annex II (without point 4) of Medical Device Directive 93/42/EEC, date of issue: 19th May, 2021, registration No: HD 1076832-1, certificate validity: 26th May 2024

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 Medicinski pripomočki – Sistem vodenja kakovosti – Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*

EN ISO 14971:2012 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*

EN ISO 15223-1:2016 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 10993-1:2020 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*

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 10993-15:2009 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 10993-18:2009 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 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 1041:2008+A1:2013 Informacije proizvajalca za medicinske pripomočke / *Information supplied by the manufacturer of medical devices*

EN ISO 22674:2016 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*

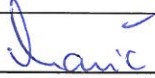
EN ISO 10271:2020 Zobozdravstvo – Preskusne metode ugotavljanja korozije za kovinske material / *Dentistry – Corrosion test methods for metallic materials*

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

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, 21.05.2021
Place, Date

Anja Mavrič, univ.dipl.biol.
Responsible person for MD and technical files


Signature:

Verzija / *Version*: 1