INTERDENT® d.o.o.
SI – 3000 CELJE – Opekarniška cesta 26
Tel.: +386 (0) 3 425-62-00 Fax: +386 (0) 3 425-62-10
E-mail: info@interdent.cc
http:// www.interdent.cc

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)

GENERIČNO IME / *GENERIC NAME*	**Material za izdelavo zobnih aparatov, PEEK / *Dental appliances fabrication material, PEEK***
TRGOVSKO IME / *TRADE NAME*	CC DISK PEEK BeePEEK Press
UMDNS / GMDN	**58288**

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 Rheniland 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 purpose*
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, označevanje in podatki, ki jih mora podati dobavitelj- 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 za ugotavljanje citotoksičnosti in vitro */ Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity*
ISO 10993-10:2010 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*

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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 10993-18:2009 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 – Del 1: Uporaba inženiringa uporabnosti medicinskih pripomočkov/ *Medical devices – Application of usability engineering to medical devices*
EN 1641:2009 Zobozdravstvo - Medicinski pripomočki za zobozdravstvo - Materiali / *Dentistry – Part 1: 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 20795-1:2013 Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / Dentistry- Base polymers – Part 1: denture base polymers
EN ISO 10477:2020 Zobozdravstvo - Polimerni materiali za prevleke in mostičke / Dentistry – *Polymer based crown and bridge materials*
EN ISO 22112:2017 Zobozdravstvo - Umetni zobje za zobne proteze / *Dentistry - Artificial teeth for dental prostheses*
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 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, 21.05.2021	Anja Mavrič, univ.dipl.biol.	
Place, Date	**Responsible person for MD and technical files**	**Signature:**

Verzija / Version: 01

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