

IZJAVA EU O SKLADNOSTI EU DECLARATION OF CONFORMITY

(v skladu s prilogo IV Uredbe o medicinskih pripomočkih (EU) 2017/745)
(in accordance with Annex IV of Medical Device Regulation (EU) 2017/745)

Podjetje/ Company: **INTERDENT® d.o.o.**
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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 I (pravilo 5) po prilogi VIII MDR,
Following Class I Products (rule 5) according to Annex VIII of the MDR,

GENERICNO IME / GENERIC NAME	CAD/CAM DISKI PMMA / CAD/CAM DISCS PMMA
TRGOVSKO IME / TRADE NAME	CC DISK PMMA (transparent, X-ray)
GMDN	42344
EMDN	Q010699
OSNOVNI UDI-DI / BASIC UDI-DI	++D058CCDISKPMMA1YP

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

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 purpose
EN ISO 9001:2015- Sistem vodenja kakovosti – zahteve / Quality management system – Requirements
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 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 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
EN ISO 7405:2018 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu / Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-5:2009: Biološko vrednotenje medicinskih pripomočkov – 5 del: Preskusi za ugotavljanje citotoksičnosti in vitro / Biological Evaluation of Medical Devices- Part 5: 2009 Testing of cytotoxicity: In vitro methods

EN ISO 10993-10:2013 Biološko vrednotenje medicinskih pripomočkov – 10.del: Preskus draženja in preobčutljivosti kože / *Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization.*

EN ISO 10993-18:2020 Biološko ovrednotenje medicinskih pripomočkov - 18. del: Kemična opredelitev lastnosti materialov za medicinske pripomočke znotraj procesov obvladovanja tveganja / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*

ISO/TS 10993-19:2020 Biološko ovrednotenje medicinskih pripomočkov - 19. del: Fizikalno-kemijska, morfološka in topografska karakterizacija materialov / *Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials*

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

ISO/TR 20416:2020 Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet / *Medical devices - Post-market surveillance for manufacturers*

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

EN 1641:2009 Zobozdravstvo - Medicinski pripomočki za zobozdravstvo - Materiali / *Dentistry – Part 1: Medical devices for dentistry - Materials*

EN ISO 10477:2020 Zobozdravstvo – Polimerni materiali za krone in mostičke / *Dentistry – Polymer based crown and bridge materials*

EN ISO 20795-1:2013 Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / *Dentistry- Base polymers – Part 1: denture base polymers*

ISO 178:2010 Plastika – Določanje lastnosti plastičnosti / *Plastic – Determination of plastic properties*

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. / *The validity of declaration of conformity is linked to a change in medical device.*

Celje, 10.05.2023

Place, Date

Anja Mavrič, B.Sc.

Responsible person for MD and technical files



Signature:

Verzija / Version: 3



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9