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IZJAVA O SKLADNOSTI
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.**
Naslov/*Address:* **Opekarniška cesta 26, SI - 3000 CELJE**
SRN številka / *SRN number:* **SI-MF-000004584**

Na lastno odgovornost izjavljamo, da sledeči proizvodi, razvrščeni v razred I (pravilo 5) po prilogi VIII MDR
We herewith declare on our sole responsibility that the following Class I Products (rule 5) according to Annex VIII of the MDR

GENERIČNO IME / *GENERIC NAME*	**BRUSNI IN POLIRNI TRAKOVI / *ABBRASIVE AND POLISHING STRIPS***
TRGOVSKO IME / *TRADE NAME*	BRUSNI IN POLIRNI TRAKOVI / *ABRASIVE AND POLISHING STRIPS* (REF 4193, REF 4194, REF 4195)
UMDNS / GMDN	**35702**
OSNOVNI UDI-DI / BASIC UDI-DI	++D058ABRPOLISHSTRIPS198

ustrezajo bistvenim zahtevam Uredbe o medicinskih pripomočkih (EU) 2017/745.
comply with essential requirements of the Medical Devices Regulation (EU) 2017/745.

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 9001:2015- Sistem vodenja kakovosti – zahteve / *Quality management system – Requirements*

EN ISO 14971:2012 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 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 – 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 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 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*

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, 25.05.2021
Place, Date

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

Signature:

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