

## 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*

<b>GENERICNO IME / GENERIC NAME</b>	<b>BRUSNI IN POLIRNI TRAKOVI / ABRASIVE AND POLISHING STRIPS</b>
<b>TRGOVSKO IME / TRADE NAME</b>	BRUSNI IN POLIRNI TRAKOVI / <i>ABRASIVE AND POLISHING STRIPS</i> (REF 4193, REF 4194, REF 4195)
<b>UMDNS / GMDN</b>	<b>35702</b>
<b>OSNOVNI UDI-DI / BASIC UDI-DI</b>	++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*

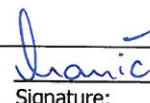
Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka. / *The validity of declaration of conformity is linked to a change in medical device.*

Celje, 25.05.2021

Place, Date

Anja Mavrič, univ. dipl. biol.

Responsible person for MD and technical files

  
Signature:

Verzija / Version: 1