Sl – 3000 CELJE – Opekarniška cesta 26
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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.**
Naslov/*Address:* **Opekarniška cesta 26, SI - 3000 CELJE**
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,

GENERIČNO IME / *GENERIC NAME*	**DENTALNI AKRILATI / *DENTAL ACRYLICS***
TRGOVSKO IME / *TRADE NAME*	INTERACRYL PLAST
GMDN	**16350**
EMDN	**Q01020199**
OSNOVNI UDI-DI / BASIC UDI-DI	++D058DENTALACRYLICS15

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 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 10993-1:2009 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 10993-1:2009/AC:2010 Biološko vrednotenje medicinskih pripomočkov – 1. del: Ocena in preskusi znootraj ocene tveganja – Technical Corrigendum 1 / *Biological Evaluation of Medical Devices- Part 1: Evaluation and testing within a risk management process - Technical Corrigendum 1*
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 10477 Zobozdravstvo – Polimerni materiali za krone in mostičke / Dentistry – Polymer based crown and bridge materials
EN ISO 20795-1 Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / Dentistry- Base polymers – Part 1: denture base polymers
ISO 178 Plastika – Določanje lastnosti plastičnosti / Plastic – Determination of plastic properties

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EN ISO 7405:2008 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu / Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-10:2013 Biološko vrednotenje medicinskih pripomočkov – 10.del: 2004 Preskuso draženja in preobčutljivosti kože / Biological evaluation of medical devices – Part 10:2004 Test for irritation and skin sensitization.

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, 23.03.2022
Place, Date

Anja Mavrič, B.Sc.
Responsible person for MD and technical files

Signature:

Verzija / Version: 2