Sl – 3000 CELJE – Opekarniška cesta 26
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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 5)
We herewith declare on our sole responsibility that the following Class IIa Products (rule 5)

GENERIČNO IME / *GENERIC NAME*	**Dentalni akrilati (za proteze) / *Dental acrylics (prosthese)***
TRGOVSKO IME / *TRADE NAME*	INTERACRYL HOT INTERACRYL COLD INTERACRYL CAST INTERACRYL ORTHO
UMDNS / GMDN	**16730**

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 Rheinland 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 - 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 1641:2009 Zobozdravstvo - Medicinski pripomočki za zobozdravstvo - Materiali / *Dentistry - 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 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 10993-5:2009 Biološko vrednotenje medicinskih pripomočkov – 5. del: Preskusi za ugotavljanje citotoksičnosti in vitro / *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*

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EN ISO 7405:2018 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu */ Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
EN ISO 20795-1:2013: Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze */ Dentistry- Base polymers – Part 1: denture base polymers*
EN ISO 20795-2:2013: Zobozdravstvo – osnovni polimeri – 2. Del: Ortodontski osnovni polimeri */ Dentistry – Base polymers – Part 2: Orthodontic base polymers*
EN 62366-1:2015 Medicinski pripomočki – Uporaba inženiringa uporabnosti medicinskih pripomočkov*/ Medical devices – Application of usability engineering to medical devices*
CR 13695-1:2000 Pakiranje – Zahteve za merjenje in verifikacijo 4 težkih kovin in ostalih nevarnih snovi, ki so prisotne v pakiranju in sproščanju v okolje – Del 1: Zahteve za merjenje in verifikacijo 4 težkih kovin v pakiranju */ Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging*
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: 1

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