

## 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<sup>®</sup> 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,*

<b>GENERICNO IME / GENERIC NAME</b>	<b>DENTALNA ODTISNA ŽLICA / DENTAL IMPRESSION TRAY</b>
<b>TRGOVSKO IME / TRADE NAME</b>	LC INTERTRAY
<b>UMDNS / GMDN</b>	16350
<b>OSNOVNI UDI-DI / BASIC UDI-DI</b>	++D058LCINTERTRAY1DZ

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 14971:2019 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 10993-18:2020 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 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*

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