INTERDENT® d.o.o.
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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 8)
We herewith declare on our sole responsibility that the following Class IIa Products (rule 8)

KORENINSKI ZATIČEK / *ROOT CANAL POST* (REF 0323)

UMDNS / GMDN Št. / No.: 16202

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: 21. 11. 2017, številka registracije: HD 60122830 0001, veljavnost certifikata: 07. 02. 2022
Conformity assessment procedure: Annex II (without point 4) of Medical Device Directive 93/42/EEC, date of issue: 21st November, 2017, registration No: HD 60122830 0001*, certificate validity: 07th Feb. 2022*
Priglašeni organ za ugotavljanje skladnosti / *Notified body*:
TÜV Rheniland 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 purposes*
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 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 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*
ISO 5832-1:2007: Vsadki za kirurgijo – Kovinski material – 1 Del: Kovno nerjaveče jeklo / *Implant for surgery – Metallic materials – Part 1: Wrought stainless steel.*
ASTM F138-13Standardna specifikacija za kovane 18Krom-14Nikelj-2,5 Molibden nerjaveče palice in žice za kirurške vsadke / *Standard specification for Wrought 18Chromium-14Nickel-2,5Molybdenum Stainless Steel Bar and Wire for Surgical Implants*

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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 62366-1:2015 Medicinski pripomočki – Del 1: Uporaba inženiringa uporabnosti medicinskih pripomočkov / Medical devices – Part 1: Application of usability engineering to medical devices
EN 1641:2009 Zobozdravstvo - Medicinski pripomočki za zobozdravstvo - Materiali / *Dentistry - Medical devices for dentistry - Materials*
EN 1041:2008 Informacije proizvajalca za medicinske pripomočke / *Information supplied by the manufacturer of medical devices*
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, 10.01.2019
Place, Date

Anja Šraj, univ. dipl. chem.
Responsible person for MD and technical files

Signature:

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Verzija / Version: 3