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)

DENTALNE ZLITINE plemenite /
DENTAL ALLOYS precious

INTERPAL (REF 0902), INTERPAL S (REF 0902S), INTERPAL SE (REF 0902SE)

UMDNS / GMDN: 16660
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 February 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, označevanje in podatki, ki jih mora podati dobavitelj- 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 znotraj 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 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 – Uporaba inženiringa uporabnosti medicinskih pripomočkov/ Medical devices – Application of usability engineering to medical devices

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EN ISO 22674:2016 Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja. */ Metallic materials for fixed and removable restorations and appliances*
EN ISO 10271:2011 Zobozdravstvc – Preskusne metode ugotavljanja korozije za kovinske material / *Dentistry – Corrosion test methods for metallic materials*
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.dpl.chem.
Responsible person for MD and technical files

Signature:

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Verzija / Version: 03