

IZJAVA O SKLADNOSTI *DECLARATION OF CONFORMITY*

Podjetje/Company:
Naslov/Address:

INTERDENT[®] d.o.o.
Opekarniška cesta 26, SI - 3000 CELJE

Na lastno odgovornost izjavljamo, da sledeči proizvodi, razreda IIa (pravilo 8)
We herewith declare on our responsibility that the following Class IIa Products (rule 8)

DENTALNE ZLITINE neplemenite ***DENTAL ALLOYS non-precious***

I BOND 02 (REF 1700, REF 1701, REF 1702, REF 1712), I BOND NF (REF 1703, REF 1704, REF 1705, REF 1713), I BOND LO (REF 1722, REF 1723, REF 1724) I GW (REF 1716, REF 1717, REF 1718), I MG (REF 1706, REF 1707, REF 1708), I MG FH (REF 1709, REF 1710, REF 1711), I MG EKO (REF 1719, REF 1720, REF 1721), I MG HE (REF 1725, REF 1726), INTERSOLDER (REF 0495), I WELD (REF 0497, REF 0498)

UMDNS Št / UMDNS No :10-077

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. 03. 2014, številka registracije: HD 60093140 0001, veljavnost certifikata: 20. 02. 2019

Conformity assessment procedure: Annex II (without point 4) of Medical Device Directive 93/42/EEC, date of issue: 19th March, 2014, registration No: HD 60093140 0001, certificate validity: 20th Feb. 2019

Priglašeni organ za ugotavljanje skladnosti / *Notified body:*

TÜV Rheinland LGA Products GmbH, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **0197**

HARMONIZIRANI STANDARDI / HARMONISED STANDARDS:

ISO 13485:2012: 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 10993-1:2009: Biološko vrednotenje medicinskih pripomočkov – 1.del: Ocena in preskusi / *Biological evaluation of medical devices – Part 1: Evaluation and testing*

EN ISO 10993-5:2009: Biološko vrednotenje medicinskih pripomočkov – 5 del: Preskusi za ugotavljanje citotoksičnosti in vitro / *Biological Evaluation of Medical Devices- Part 5: 2009 Testing of cytotoxicity: In vitro methods,*

EN ISO 22674:2006: Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja / *Metallic materials for fixed and removable restorations and appliances*

EN ISO 9693-1:2012 Zobozdravstvo – preskušanje združljivosti – 1. Del: Kovinsko-keramični sistemi / *Dentistry – compatibility testing – Part 1: Metal-ceramic systems*

EN 62366:2008: Medicinske naprave – Uporaba inženirstva uporabljivosti pri medicinskih napravah / *Medical devices – Application of usability engineering to medical devices*

EN ISO 9333:2006: Zobozdravstvo – materiali za spajkanje / *dentistry – brazing materials*

EN ISO 10271:2011 Zobozdravstvo - Preskusne metode ugotavljanja korozije za kovinske materiale / *Dentistry – Corrosion test methods for metallic materials*

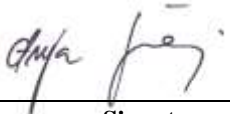
EN ISO 15223-1:2012: Medicinski pripomočki – Simboli za označevanje medicinskih pripomočkov, označevanje in podatki, ki jih mora podati dobavitelj- 1.del: Splošne zahteve / *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – part 1: general requirements*

Celje, 24. 10. 2016

Place, Date

Anja Šraj, univ.dpl.chem.

Responsible person for MD and technical files



Signature:

Št. / No.: 7