Sl – 3000 CELJE – Opekarniška cesta 26
Tel.: +386 (0) 3 425-62-00 Fax: +386 (0) 3 425-62-10
E-mail: info@interdent.cc
http:// www.interdent.cc

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 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 Rheniland 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 citotoxicity: In vitro methods,*

INTERDENT® d.o.o.
Sl – 3000 CELJE – Opekarniška cesta 26
Tel.: +386 (0) 3 425-62-00 Fax: +386 (0) 3 425-62-10
E-mail: info@interdent.cc
http:// www.interdent.cc

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 — Anja Šraj, univ.dpl.chem. — **Signature:**
Place, Date — **Responsible person for MD and technical files**

Št. / No.: 7