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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 responsibility that the following Class IIa Products (rule 8)

DENTALNE ZLITINE / *DENTAL ALLOYS*

I BOND 02 (REF 1700, REF 1701, REF 1702, REF 1712), *I BOND NF* (REF 1703, REF 1704, REF 1705, REF 1713), *I CV* (REF 1715), *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 1720, REF 1721, REF 1721), *INTERSOLDER* (REF 0495), *I WELD* (REF 0497)

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. 01. 2009, številka registracije: 1881869-006-000, veljavnost certifikata: 18. 01. 2014
Conformity assessment procedure: Annex II (without point 4) of Medical Device Directive 93/42/EEC, date of issue: january 19, 2009, registration No: 1881869-006-000, certificate validity: january 18, 2014
Priglašeni organ za ugotavljanje skladnosti / *Notified body*:
LGA Intercert, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **1275**

HARMONIZIRANI STANDARDI / *HARMONISED STANDARDS:*
ISO 13485:2003+AC 2009: Medicinski pripomočki – Sistem vodenja kakovosti-Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2009 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 22674:2006: Zobozdravstvo – kovinski materiali za stalne in zamenljive zobne obnove in orodja / *Metallic materials for fixed and removable restorations and appliances*
EN ISO 10993-5:Biološko ovrednotenje medicinskih pripomočkov – 5.del: Preiskusi za ugotavljanje citotoksičnosti in vitro / *Biological evaluation of medical devices – Part 5: Test for in vitro toxicity*

Celje, 03.10.2011 — **Place, Date**
Anja Šraj, univ.dpl.chem. — **Responsible person for MD and technical files**
Signature: