

IZJAVA O SKLADNOSTI *DECLARATION OF CONFORMITY*

(v skladu z dodatkom VII Direktive za medicinske pripomočke 93/42/EGS)
(in accordance with Annex VII of Medical device directive 93/42/EEC)

Podjetje/Company:

INTERDENT[®] d.o.o.

Naslov/Address:

Opekarniška cesta 26, SI - 3000 CELJE

Na lastno odgovornost izjavljamo, da sledeči proizvodi, razreda I (pravilo 5)

We herewith declare on our responsibility that the following Class I Products (rule 5)

ARTIKULACIJSKA FOLIJA / ARTICULATING FOIL

(REF 0099, REF 0991, REF 0992, REF 0993, REF 0099-30, REF 0991-30, REF 0992-30, REF 0993-30, REF 0994, REF 0995, REF 0996, REF 0997, REF 0994-30, REF 0995-30, REF 0996-30, REF 0997-30)

ustrezajo bistvenim zahtevam Direktive o medicinskih pripomočkih 93/42/EGS.
comply with essential requirements of the Medical Devices Directive 93/42 EEC.

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*

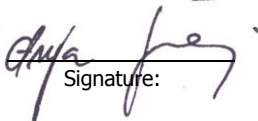
EN ISO 14971:2012 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*

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 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, 24.03.2014
Place, Date

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


Signature: