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# 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)*

## INTERACRYL PLAST

(REF 1520, REF 1522, REF 1524, REF 1523)

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*

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Celje, 24. 03. 2014
Place, Date

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

Signature: