



SI – 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](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 5)
We herewith declare on our responsibility that the following Class IIa Products (rule 5)

Bazni akrilati za proteze / *Dental acrylics.*

INTERACRYL HOT

prah barva 3/ *powder colour 3* (REF 1505, REF 1503)
prah barva 10/ *powder colour 10* (REF 1504, REF 1502)
prah barva 5/ *powder colour 5* (REF 1564, REF 1570)
prah barva 15/ *powder colour 15* (REF 1580, REF 1581)
prah barva 16/ *powder colour 16* (REF 1593, REF 1592)
prah prozoren/ *powder transparent* (REF 1560, REF 1561)
tekočina/ *liquid* (REF 1506)

INTERACRYL COLD

prah barva 3/ *powder colour 3* (REF 1508, REF 1512, REF 1510, REF 1546)
prah barva 5/ *powder colour 5* (REF 1571, REF 1567, REF 1566, REF 1565), prah barva
10/ *powder colour 10* (REF 1507, REF 1511, REF 1509, REF 1545)
prah barva 15/ *powder colour 15* (REF 1588, REF 1585, REF 1586, REF 1587)
prah barva 16/ *powder colour 16* (REF 1589, REF 1590, REF 1597, REF 1591)
prah prozoren/ *powder transparent* (REF 1562)
tekočina / *liquid* (REF 1514, REF 1513, REF 1547)

INTERACRYL CAST

prah barva 3/ *powder colour 3* (REF 1516, REF 1518, REF 1549)
prah barva 5/ *powder colour 5* (REF 1572, REF 1569, REF 1568)
prah barva 10/ *powder colour 10* (REF 1515, REF 1517, REF 1548)
prah barva 15/ *powder colour 15* (REF 1584, REF 1582, REF 1583)
prah barva 16/ *powder colour 16* (REF 1594, REF 1595, REF 1596)
tekočina/ *liquid* (REF 1519, REF 1550)

INTERACRYL ORTHO

prah prozoren/ *powder transparent* (REF 1526)
tekočina prozorna/ *liquid transparent* (REF 1533, REF 1527)
tekočina roza/ *liquid pink* (REF 1534, REF 1528)
tekočina rdeča/ *liquid red* (REF 1535, REF 1529)
tekočina modra/ *liquid blue* (REF 1536, REF 1530)
tekočina zelena/ *liquid green* (REF 1537, REF 1531)
tekočina rumena/ *liquid yellow* (REF 1532, REF 1538)
set (REF 1525)

UMDNS Št / *UMDNS No* : 16-728

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 20795-1:2008/AC:2009: Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / *Dentistry- Base polymers – Part 1: denture base polymers*

EN ISO 20795-2:2010: Zobozdravstvo – osnovni polimeri – 2. Del: Ortodontski osnovni polimeri / *Dentistry – Base polymers – Part 2: Orthodontic base polymers*

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

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, 08. 04. 2014

Place, Date

Anja Šraj, univ.dpl.chem.

Responsible person for MD and technical files



Signature: