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IZJAVA EU O SKLADNOSTI
EU DECLARATION OF CONFORMITY

Podjetje/*Company*: **INTERDENT® d.o.o.**
Naslov/*Address:* **Opekarniška cesta 26, SI - 3000 CELJE**
SRN: **SI-MF-000004584**

Izjavljamo, da smo kot proizvajalec izključno odgovorni za izdajo izjave EU o skladnosti. /
We declare, that as a manufacturer, we are solely responsible for issuing the EU declaration of conformity.

Sledeči proizvodi, razvrščeni v razred IIa (pravilo 5) po prilogi VIII MDR,
Following Class IIa Products (rule 5) according to Annex VIII of the MDR,

GENERIČNO IME / *GENERIC NAME*	**DENTALNI AKRILATI / *DENTAL ACRYLICS***
TRGOVSKO IME / *TRADE NAME*	INTERACRYL HOT INTERACRYL COLD INTERACRYL CAST INTERACRYL ORTHO
GMDN	**16730**
EMDN	Q010699
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058DENTALACRYLICS2AF7

ustrezajo splošnim zahtevam glede varnosti in učinkovitosti Uredbe o medicinskih pripomočkih (EU) 2017/745 (MDR).
comply with general safety and performance requirements of the Medical Devices Regulation (EU) 2017/745 (MDR).
Postopek ugotavljanja skladnosti: Dodatek IX, Poglavje I in III Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 25.11.2025, številka registracije: HZ 1076832-1, veljavnost certifikata: 09.05.2028 *Conformity assessment procedure: Annex IX, Chapter I and III of Medical Devices Regulation (EU) 2017/745, date of issue:* 25.11.2025, *registration No:* HZ 1076832-1, *certificate validity:* 09.05.2028
Priglašeni organ za ugotavljanje skladnosti / *Notified body*:
TÜV Rheinland LGA Products Gmbh, Tillystrasse 2, D – 90431 Nürnberg – številka / *number* **0197**

HARMONIZIRANI IN OSTALI STANDARDI / *HARMONISED AND OTHER STANDARDS:*
EN ISO 13485:2016+A11:2021 Medicinski pripomočki – Sistem vodenja kakovosti – Zahteve za zakonodajne namene / *Medical devices – Quality management systems – Requirements for regulatory purposes*
EN ISO 14971:2019/A11:2021 Medicinski pripomočki-Uporaba obvladovanja tveganja pri medicinskih pripomočkih / *Medical devices - Application of risk management to medical devices*
CEN ISO/TR 24971:2020 Medicinski pripomočki - Navodilo za uporabo ISO 14971 / *Medical devices – Guidance on the application of ISO 14971*
EN ISO 15223-1:2021/A1:2025 Medicinski pripomočki – Simboli za označevanje medicinskih pripomočkov - 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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EN ISO 10993-1:2026 Biološko ovrednotenje medicinskih pripomočkov - 1. del: Zahteve in splošna načela za oceno biološke varnosti znotraj procesa obvladovanja tveganja */ Biological Evaluation of Medical Devices- Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*
EN ISO 10993-3:2014 Biološko vrednotenje medicinskih pripomočkov – 3. del: Preskusi za genotoksičnost, rakotvornost in reproduktivno toksičnost / Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009/A11:2025 Biološko vrednotenje medicinskih pripomočkov – 5. del: Preskusi zaugotavljanje citotoksičnosti in vitro / Biological Evaluation of Medical Devices- Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-9:2021 Biološko ovrednotenje medicinskih pripomočkov - 9. del: Okvirni sistem za prepoznavanje in ugotavljanje količine morebitnih razgradnih produktov / *Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products*
EN ISO 10993-10:2023 Biološko vrednotenje medicinskih pripomočkov – 10. del: Preskusi za draženje in preobčutljivost kože. / Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2018 Biološko vrednotenje medicinskih pripomočkov – 11. del: Preskusi za sistemsko toksičnost */ Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
EN ISO 10993-12:2021/A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 12. del: Priprava vzorcev in referenčni materiali */ Biological evaluation of medical devices - Part 12: Sample preparation and reference materials*
EN ISO 10993-17:2023 /A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 17. del: Postavitev dopustnih mej za izlužene snovi */ Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances*
EN ISO 10993-18:2020/A1:2023 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu */ Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
EN ISO 7405:2025 Zobozdravstvo – Ocena biokompatibilnosti medicinskih pripomočkov v zobozdravstvu */ Dentistry – Evaluation of biocompatibility of medical devices used in dentistry*
EN 62366-1:2015/A1:2020 Medicinski pripomočki – Uporaba inženiringa uporabnosti medicinskih pripomočkov*/ Medical devices – Application of usability engineering to medical devices*
EN 1641:2009 Zobozdravstvo. Medicinski pripomočki za zobozdravstvo. Materiali / *Dentistry. Medical devices for dentistry. Materials.*
CEN ISO/TR 20416:2020 Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet / *Medicinski pripomočki - Nadzor proizvajalcev po dajanju v promet*
EN ISO 20417:2021 Informacije proizvajalca za medicinske pripomočke / *Information supplied by the manufacturer of medical devices*
EN ISO 20795-1:2013: Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze / Dentistry- Base polymers – Part 1: denture base polymers
EN ISO 20795-2:2013: Zobozdravstvo – osnovni polimeri – 2. Del: Ortodontski osnovni polimeri / Dentistry – Base polymers – Part 2: Orthodontic base polymers
EN ISO 10477:2020 Zobozdravstvo - Polimerni materiali za prevleke in mostičke / Dentistry – Polymer based crown and bridge materials
ISO 178:2010 Polimerni materiali - Določanje upogibnih lastnosti / Plastic – Determination of plastic properties
ISO/TS 10993-19:2020 Biological evaluation of medical devices – Part 19: Physico-chemical, morphological and topographical characterization of materials
EN ISO 10993-23:2021/A1:2025 Biološko ovrednotenje medicinskih pripomočkov - 23. del: Preskusi draženja / *Biological evaluation of medical devices – Part 23: Tests for irritation*
ISO/TS 21726:2019 Biološko vrednotenje medicinskih pripomočkov – Uporaba praga toksikološke zaskrbljenosti (TTC) za oceno biokompatibilnosti sestavin medicinskih pripomočkov / *Biological evaluation of medical devices – Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents*

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EN ISO 9001:2015/A1:2024 Sistem vodenja kakovosti – zahteve */ Quality management system – requirements*
CR 13695-1:2000 Embalaža - Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži ter njihov izpust v okolje - 1. del: Zahteve za merjenje in overjanje štirih težkih kovin in drugih nevarnih snovi v embalaži / *Packaging – Requirements for measuring and verifying the four heavy metals and other dangerous substances present in packaging and their release into the environment – Part 1: Requirements for measuring and verifying the four heavy metals present in packaging*
EN ISO 4180:2019 Embalaža - Celovita, napolnjena transportna embalaža - Splošna pravila za pripravo programov preskušanja primernosti za uporabo / *Packaging – Complete, filled transport packages – General rules for the compilation of performance test schedules*

ANSI/HIBC 2.6 standard 2016: Standard označevanja dobaviteljev zdravstvene industrije za varnost pacientov in edinstveno identifikacijo naprave (UDI) */ The health industry supplier labeling standard for patient safety & unique device identification (UDI)*

Veljavnost izjave o skladnosti je vezana na spremembo medicinskega pripomočka ali na veljavnost certifikata priglašenega organa. */ The validity of declaration of conformity is linked to a change in medical device or on validity of certificate issued by notified body.*

Celje, 10.04.2026 — **Place, Date**

Anja Mavrič, B.Sc. — **Responsible person for regulatory compliance (MDR, Article 15 (3): (b) & (c))**

Signature:

Verzija / *Version*: MDR 1

ANNEX TO DECLARATION OF CONFORMITY VERSION MDR 1 – ALL REF COVERED:

REF	DESCRIPTION	UDI-DI
1502	Interacryl Hot Set, colour 10	+D05800000000015020
1503	Interacryl Hot Set, colour 3	+D05800000000015030
1504	Interacryl Hot Powder, colour 10, 1000 g	+D05800000000015040
1505	Interacryl Hot Powder, colour 3, 1000 g	+D05800000000015050
1506	Interacryl Hot Liquid 500 ml	+D05800000000015060
1507	Interacryl Cold Set, colour 10	+D05800000000015070
1508	Interacryl Cold Set, colour 3	+D05800000000015080
1509	Interacryl Cold Powder, colour 10, 350 g	+D05800000000015090
1510	Interacryl Cold Powder, colour 3, 350 g	+D05800000000015100
1511	Interacryl Cold Powder, colour 10, 100 g	+D05800000000015110
1512	Interacryl Cold Powder, colour 3, 100 g	+D05800000000015120
1513	Interacryl Cold Liquid for colour 3,5,15, 250 ml	+D05800000000015130
1514	Interacryl Cold Liquid for colour 3,5,15, 100 ml	+D05800000000015140
1515	Interacryl Cast Set, colour 10	+D05800000000015150
1516	Interacryl Cast Set, colour 3	+D05800000000015160
1517	Interacryl Cast Powder, colour 10, 350 g	+D05800000000015170
1518	Interacryl Cast Powder, colour 3, 350 g	+D05800000000015180
1519	Interacryl Cast Liquid for colour 3,5,15, 250 ml	+D05800000000015190
1525	Interacryl ortho Set	+D05800000000015250
1526	Interacryl Ortho Powder, 1000 g	+D05800000000015260

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1527	Interacryl Ortho Liquid transparent 500 ml	+D05800000000015270
1528	Interacryl Ortho Liquid, pink, 500 ml	+D05800000000015280
1533	Interacryl Ortho Liquid, transparent, 100 ml	+D05800000000015330
1545	Interacryl Cold Powder, colour 10, 1000 g	+D05800000000015450
1546	Interacryl Cold, Powder, colour 3, 1000 g	+D05800000000015460
1547	Interacryl Cold Liquid 500 ml	+D05800000000015470
1548	Interacryl Cast Powder, colour 10, 1000 g	+D05800000000015480
1549	Interacryl Caste Powder, colour 3, 1000 g	+D05800000000015490
1550	Interacryl cast liquid for colour 3,5,15, 500 ml	+D05800000000015500
1560	Interacryl Hot Set transparent	+D05800000000015600
1561	Interacryl Hot Powder, transparent, 1000 g	+D05800000000015610
1562	Interacryl Cold Powder, transparent, 350 g	+D05800000000015620
1563	Interacryl Cold Powder, transparent, 1000 g	+D05800000000015630
1564	Interacryl Hot powder, colour 5, 1000 g	+D05800000000015640
1565	Interacryl Cold powder, colour 5, powder 1000 g	+D05800000000015650
1566	Interacryl Cold powder, colour 5, 350 g	+D05800000000015660
1567	Interacryl Cold powder, colour 5, 100 g	+D05800000000015670
1568	Interacryl Cast powder, colour 5, 1000 g	+D05800000000015680
1569	Interacryl Cast powder, colour 5, 350 g	+D05800000000015690
1570	Interacryl Hot Set, colour 5	+D05800000000015700
1571	Interacryl Cold Set colour 5	+D05800000000015710
1572	Interacryl Cast Set, colour 5	+D05800000000015720
1580	Interacryl Hot powder, colour 15, 1000 g	+D05800000000015800
1581	Interacryl Hot set, 15	+D05800000000015810
1582	Interacryl Cast powder, colour 15, 350 g	+D05800000000015820
1583	Interacryl Cast powder, colour 15, 1000 g	+D05800000000015830
1584	Interacryl Cast set 15	+D05800000000015840
1585	Interacryl Cold powder, colour 15, powder 100 g	+D05800000000015850
1586	Interacryl Cold powder, colour 15, powder 350 g	+D05800000000015860
1587	Interacryl Cold powder, colour 15, powder 1000 g	+D05800000000015870
1588	Interacryl Cold set, 15	+D05800000000015880
1552	INTERACRYL CAST LIQUID FOR COLOUR 10, 500 ml	+D05800000000015510
1551	INTERACRYL CAST LIQUID FOR COLOUR 10, 250 ml	+D05800000000015520
1553	INTERACRYL COLD LIQUID FOR COLOUR 10, 100 ml	+D05800000000015530
1554	INTERACRYL COLD LIQUID FOR COLOUR 10, 250 ml	+D05800000000015540
1555	INTERACRYL COLD LIQUID FOR COLOUR 10, 500 ml	+D05800000000015550