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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 8) po prilogi VIII MDR,
Following Class IIa Products (rule 8) according to Annex VIII of the MDR,

GENERIČNO IME / *GENERIC NAME*	**Material za izdelavo zobnih aparatov, PEEK / *Dental appliances fabrication material, PEEK***
TRGOVSKO IME / *TRADE NAME*	CC DISK PEEK BeePEEK Press
GMDN	58288
EMDN	Q010699
OSNOVNI UDI-DI / *BASIC UDI-DI*	++D058PEEKMATERIAL2AY6

ustrezajo splošnim zahtevam glede varnosti in učinkovitosti Uredbe o medicinskih pripomočkih (EU) 2017/745.
comply with general safety and performance requirements of the Medical Devices Regulation (EU) 2017/745.
Postopek ugotavljanja skladnosti: Dodatek IX, Poglavje I Uredbe o medicinskih pripomočkih (EU) 2017/745, datum izdaje: 10.05.2023, številka registracije: HZ1076832-1, veljavnost certifikata: 09.05.2028 *Conformity assessment procedure: Annex IX, Chapter I of Medical Devices Regulation (EU) 2017/745, date of issue:* 10.05.2023*, registration No:* HZ1076832-1*, 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*
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

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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 10993-6:2016 Biološko vrednotenje medicinskih pripomočkov – 6. del: Preskusi za lokalne učinke po vstavitvi vsadkov. / Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
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 Biološko vrednotenje medicinskih pripomočkov – 18. del: Kemijska opredelitev materialov / *Biological evaluation of medical devices – Part 18: Chemical characterization of materials*
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*
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*
EN ISO 20795-1:2013 Zobozdravstvo – Osnovni polimeri – 1. Del: Osnovni polimeri za proteze */ Dentistry- Base polymers – Part 1: denture base polymers*
EN ISO 10477:2020 Zobozdravstvo - Polimerni materiali za prevleke in mostičke */ Dentistry – Polymer based crown and bridge materials*
EN ISO 22112:2017 Zobozdravstvo - Umetni zobje za zobne proteze */ Dentistry - Artificial teeth for dental prostheses*
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*

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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 — Anja Mavrič, B.Sc.

Place, Date — **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	UDI-DI	DESCRIPTION (colour, thickness / content)
1410	+D058000000000014100	CC DISK PEEK Ivory 12 mm
1411	+D058000000000014110	CC DISK PEEK Ivory 14 mm
1412	+D058000000000014120	CC DISK PEEK Ivory 16 mm
1413	+D058000000000014130	CC DISK PEEK Ivory 18 mm
1414	+D058000000000014140	CC DISK PEEK Ivory 20 mm
1415	+D058000000000014150	CC DISK PEEK Ivory 25 mm
1420	+D058000000000014200	CC DISK PEEK white 12 mm
1421	+D058000000000014210	CC DISK PEEK white 14 mm
1422	+D058000000000014220	CC DISK PEEK white 16 mm
1423	+D058000000000014230	CC DISK PEEK white 18 mm
1424	+D058000000000014240	CC DISK PEEK white 20 mm
1425	+D058000000000014250	CC DISK PEEK white 25 mm
1431	+D058000000000014310	CC DISK PEEK pink 14 mm
1432	+D058000000000014320	CC DISK PEEK pink 16 mm
1433	+D058000000000014330	CC DISK PEEK pink 18 mm
1434	+D058000000000014340	CC DISK PEEK pink 20 mm
1435	+D058000000000014350	CC DISK PEEK pink 25 mm
1400	+D058000000000014000	BeePEEK Press Ivory, 25 g
1401	+D058000000000014010	BeePEEK Press Ivory, 100 g