

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,

GENERICNO IME / GENERIC NAME	Attachments / Polzila
TRGOVSKO IME / TRADE NAME	ACRYLOCK (matrica / matrix)
EMDN	Q010699
OSNOVNI UDI-DI / BASIC UDI-DI	++D058ACRYLOCKATTACH2AUA

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*

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 10993-6:2026 Biološka ocena medicinskih pripomočkov - 6. del: Preskusi lokalnih učinkov po vsaditvi / *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

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: Postavitve 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 20417:2026 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*

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*

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 priglašene 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, 16.06.2026

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	UDI-DI	DESCRIPTION
4322	+D05800000000043220	ACRYLOCK MATRIX, GREENE, 10 pcs
4323	+D05800000000043230	ACRYLOCK MATRIX, YELLOW, 10 pcs
4324	+D05800000000043240	ACRYLOCK MATRIX, RED, 10 pcs