EU Declaration of Conformity

Name of manufacturer:	UAB “Medicinos linija“
Single registration number:	LT-MF-000002719
Basic UDI-DI	4772178ML13DHMMTZ
Registered place of business and address of manufacturer:	Aviacijos str. 28, LT-77103 Siauliai, Lithuania
Date of issue of the declaration:	10th of April 2025
Place of issue:	Siauliai
Expiry date:	09th of April 2030

Medical device family:	Dental handpieces maintenance materials
Medical device name:	Dental handpieces heads oil
Intended purpose:	Dental handpieces heads oil is intended for use during maintenance dental handpieces for lubrication of all kind of dental handpieces.

Medical device trade names and specification:

Medical device trade name	***Catalogue number (REF)***	***Specification***
i-OIL	IHSCP	500ml

- This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
- Risk class of the device:
  - Class I, according to regulation (EU) 2017/745 of the European Parliament and of the Council Annex VIII, rule 1.
- Medical device Complies with the fundamental requirements for medical devices listed in (EU) 2017/745 of the European Parliament and of the Council Annex I.
- Standards and common specifications applied:

EN ISO 13485:2016 Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016); EN ISO 13485:2016/AC:2018 Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485:2016); EN ISO 13485:2016+A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016); EN ISO 14971: 2019 Medical devices. Application of risk management to medical devices (ISO 14971:2019); EN ISO 14971: 2019/A11:2021 Medical devices - Application of risk management to medical devices (ISO 14971:2019); EN ISO 7405:2025 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2025); EN ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2025); EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020); IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015); IEC TR 62366-2:2016 Medical devices – Part 2: Guidance of the application of usability engineering to medical devices (IEC TR 62366-2:2016); EN ISO 15223-1:2021/Amd 1:2025 "Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements — AMENDMENT 1:

Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific" (EN ISO 15223-1:2021/Amd 1:2025); EN ISO 20417:2021 Medical devices – Information supplied by the manufacturer of medical devices (EN ISO 20417:2021); EN 1641:2009 Dentistry – Medical devices for dentistry – Materials (EN 1641:2009); MEDDEV 2.7/1: 2016 rev.4 Clinical evaluation: Guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC; MEDDEV 2.12/1: 2013 rev.8 Guidelines on a Medical devices Vigilance system; MEDDEV 2.12/2: 2012 rev.2 Post market clinical follow-up studies a guide for manufacturers and notified bodies; MEDDEV 2.2/3 rev.3, 1998 "USE-BY" date

- Referenced technical documentation is retained under the premises of the manufacturer.

On behalf of UAB "Medicinos linija",

General Manager _____ Linas Tamošiūnas

Quality Executive Manager _____ Austėja Normontienė

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