i-dental | Innovative Dental Products

UAB "Medicinos linija"
Aviacijos str. 28, LT-77103 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
E-mail: info@i-dental.lt
Website: www.i-dental.lt

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: 26th of May 2021
Place of issue: Siauliai
Expiry date: 26th of May 2026

Medical device family: Dental handpieces maintenance materials

Medical device name: Dental handpieces heads oil

Intended use: 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
dline Universal Handpiece Oil Spray	25000	500ml
LUBRIPRO500	KL-OL500	500ml

- This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
- Risk class of the device:
  - Class I, according 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

Bank: LUMINOR BANK AS
Konstitucijos ave. 21A, Vilnius, Lithuania
SWIFT: AGBLLT2XXXX
IBAN: LT62 4010 0510 0433 2852

Bank: AB SEB bankas
Gedimino ave. 12, Vilnius, Lithuania
SWIFT: CBVILT2X
IBAN: LT04 7044 0600 0235 9648

UAB "Medicinos linija"
Aviacijos str. 28, LT-77103 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
E-mail: info@i-dental.lt
Website: www.i-dental.lt

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 7405:2018 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2018, Corrected version 2018-12); EN ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018); EN ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03); EN 1041: 2008+A1:2013 Information supplied by the manufacturer of medical devices; EN 1641:2009 Dentistry - Medical devices for dentistry – Materials; MEDDEV 2.7/1 rev.4, 2016 Clinical evaluation: a guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC; MEDDEV 2.12/1 rev.8, 2013 Guidelines on a medical devices vigilance system; MEDDEV 2.12/2 rev.2, 2012 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 _____ Rima Žurauskaitė-Storace

Quality Executive Manager _____ Simona Daunienė

Digitally signed by Bolgari Irina
Date: 2023.05.22 16:54:05 EEST
Reason: MoldSign Signature
Location: Moldova

Bank: LUMINOR BANK AS
Konstitucijos ave. 21A, Vilnius, Lithuania
SWIFT: AGBLLT2XXXX
IBAN: LT62 4010 0510 0433 2852

Bank: AB SEB bankas
Gedimino ave. 12, Vilnius, Lithuania
SWIFT: CBVILT2X
IBAN: LT04 7044 0600 0235 9648