EU Declaration of Conformity

Name of manufacturer:	UAB “Medicinos linija“
Single registration number:	LT-MF-000002719
Basic UDI-DI	4772178ML-LCNFC26
Registered place of business and address of manufacturer:	Aviacijos str. 28, LT-77103 Siauliai, Lithuania
Date of issue of the declaration:	2025-04-10
Place of issue:	Siauliai
Expiry date:	2030-04-09
Notified body:	BSI Group The Netherlands B.V., Notified Body No. 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, the Netherlands
CE certificate No.:	MDR 790107

Medical device family:	Polymer-based restorative materials
Medical device name:	Light curing nano flowable composite
Intended purpose:	Light curing nano flowable composite restores/improves aesthetic appearance of restorable tooth; restores/maintains dental function of restorable tooth; protects biological structures of restorable tooth and adjacent tissue.

Medical device trade names and specification:

Medical device trade name	*Catalogue number (REF)*	*Specification*
i-FLOW N	IFSA1	0.5g syringe shade, 1 tip
	IFTA1	2g syringe shade A1, 3 tips
	IFLA1	5g syringe shade A1, 5 tips
	IFSA2	0.5g syringe shade A2, 1 tip
	IFTA2	2g syringe shade A2, 3 tips
	IFLA2	5g syringe shade A2, 5 tips
	IFSA3	0.5g syringe shade A3, 1 tip
	IFTA3	2g syringe shade A3, 3 tips
	IFLA3	5g syringe shade A3, 5 tips
	IFTA35	2g syringe shade A3.5, 3 tips
	IFLA35	5g syringe shade A3.5, 5 tips
	IFTB2	2g syringe shade B2, 3 tips
	IFTK1	4x2g syringes shades under request, 10 tips
	IFLB2	5g syringe, shade B2, 5 tips

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

– Class IIa according to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex VIII, rule 8.

- The devices that are covered by the present declaration are in conformity with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and, if applicable, with any relevant Union legislation that provides for the issuing of an EU declaration of conformity and bear CE 2797 mark to indicate conformity of aforementioned devices with the provisions of this Regulation.
- The Notified Body has assessed the conformity of medical devices and audited UAB „Medicinos linija“ quality assurance system in accordance to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Annex IX, Chapters I–III, and found that the medical devices and quality assurance system meet the requirements (EU Quality Management System Certificate No. MDR 790107, Notified Body BSI Group The Netherlands B.V. (No. 2797)).
- 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 10993-1:2018); EN ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2021); EN ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference material (ISO 10993-12:2021); EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023); 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); EN ISO 10993-23:2021 Biological evaluation of medical devices – Part 23: Tests for irritation (ISO 10993-23:2021); EN ISO 14155:2020/A11:2024 Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2020/A11:2024); 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); EN ISO 4049:2019 Dentistry – Polymer-based restorative materials (ISO 4049:2019); 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

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Quality Executive Manager _____ Austėja Normontienė

Document change history

Revision date	Change description	Established	Signature
2025-05-08, v1	Replaced EC Certificate No. CE 654572 with EU Quality Management System Certificate No. MDR 790107	Quality Assurance Manager, Jovita Nemeikštytė Trumpienė	-
2025-07-11, v2	Included REFs to elitis flow: PDPS26; PDPS27; updated i-FLOW N REF IFLB2 content; all REFs content info updated - IFU kept only for REF with paper IFU included.	Quality Assurance Manager, Jovita Nemeikštytė Trumpienė	-
2025-10-02, v3	Used chapters (I-III) included to annex IX. Applied standard ISO 7405:2025 updated. General Manager and Quality Executive Manager persons changed.	Quality Assurance Manager, Virginija Gubanovaitė	-
2025-11-05, v4	New brand names included: ASTER FLOW +, Elegance Flow.	Quality Assurance Manager, Virginija Gubanovaitė	-
2026-03-20, v5	Updated applicable standard from EN ISO 14155:2020 to EN ISO 14155:2020/A11:2024	Quality Assurance Manager, Jovita Nemeikštytė Trumpienė	