i-dental Innovative Dental Products

UAB "Medicinos Linija"
Karaliaučiaus str. 29, LT-78348 Šiauliai, Lithuania
Reg. No.: 145889060
VAT No.: LT458890610

Tel.: +370 41 553 553
E-mail: info@i-dental.lt
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EC Declaration of Conformity

Name of manufacturer: UAB „Medicinos linija"
Address of manufacturer: Karaliauciaus str. 29, LT-78348 Siauliai, Lithuania
Declaration date: 4th of February 2020
Declaration expiry date: 26th of May 2024

Notified body: BSI Group The Netherlands B.V., Notified Body No. 2797
Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, the Netherlands

Medical devices:

Medical device name	*Trade name*
Light curing nano flowable composite	i-FLOW N dline Light Curing Nano Flowable Composite OCTOLIGHT Flow elitis flow

We herewith declare that:

- The above mentioned products meet the provisions of Council Directive 93/42/EEC Concerning Medical Devices amended by Directive 2007/47/EC of the European Parliament and of the Council (hereinafter Directive) and bear CE 2797 mark to indicate conformity of aforementioned products with the provisions of these Directives.
- The above mentioned products have been classified in IIa class according to Annex IX rule 8 of Directive.
- The Notified Body has assessed the conformity of medical devices and audited UAB „Medicinos linija" quality assurance system in accordance to Directive 93/42/EEC Concerning Medical Devices, Annex II excluding Section 4, as amended and found that the medical devices and quality assurance system meets the requirements (EC certificate No. CE 654572, Notified Body BSI Group The Netherlands B.V. (No. 2797)). This EC Declaration of Conformity has the same expiry date as the aforementioned EC Certificate.
- Referenced technical documentation is retained under the premises of the manufacturer.
- Standards 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 14971: 2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019); 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 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014); EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); EN ISO 10993-6:2016 Biological evaluation of medical devices – Part 6: Tests for local effects after implantation (ISO 10993-6:2016); EN ISO 10993-10:2013 Biological

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SIAULIAI CHAMBER OF COMMERCE, INDUSTRY AND CRAFTS

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evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010); EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017); EN ISO 10993-18:2005 Biological evaluation of medical devices – Part 18: Chemical characterization of materials (ISO 10993-18:2005); EN ISO/TS 10993-19:2006 Biological evaluation of medical devices — Part 19: Physico-chemical, morphological and topographical characterization of materials (ISO/TS 10993-19:2006); 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; 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; MEDDEV 2.12/1: 2013 rev.8 Guidelines on a Medical Devices Vigilance System; MEDDEV 2.12/2: 2012 rev.2 Guidelines on a Medical Devices Post Market Clinical Follow-Up Studies a Guide for Manufacturers and Notified Bodies; MEDDEV 2.2/3: 1998 rev.3 "USE-BY" date.

General Manager _____ Gintaras Dapkus

Quality Executive Manager _____ Geda Zuokaitė

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bsi. ISO 13485 Medical Devices Quality Management
MD 654577

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