

# EC Declaration of Conformity

**Name of manufacturer:** UAB „Medicinos linija“  
**Address of manufacturer:** Karaliaučiaus str. 29, LT-78348 Siauliai, Lithuania  
**Declaration date:** 4<sup>th</sup> of February 2020  
**Declaration expiry date:** 26<sup>th</sup> 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:

<i>Medical device name</i>	<i>Trade name</i>
Phosphoric acid etching gel and liquid	i-GEL N dline Phosphoric acid etching gel dline Phosphoric acid etching liquid OCTACID Green Blu-Gel elitis etch OCTACID Green Jeringa 12g (9ml) Bossklein MAXI Jumbo Etching Gel Bossklein Etching Gel Syringe

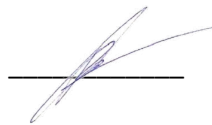
### We herewith declare that:

- 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 6 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:2016 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); 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 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009); EN ISO 10993-10:2013 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010); EN ISO 10993-11:2017 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; 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 rev.3, 1998 "USE-BY" date.*

General Manager



Gintaras Dapkus

Quality Executive Manager



Geda Zuokaitė