

DECLARATION OF CONFORMITY

for SGR-28 Resin

Document No.: QF-010-023-003 Revision: 01

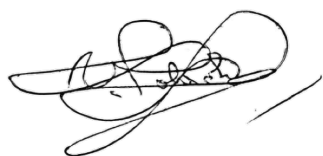
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices as amended by Regulation (EU) 2020/561

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name	Ameralabs SGR-28
Legal manufacturer	Labsamera, MB. Draugystes g. 14, 51259, Kaunas, Lithuania
Manufacturer's SRN	LT-MF-000056990
Basic UDI-DI	477904945SGR28NJ
Variants	None
Intended purpose	SGR-28 resin is a light-curable polymer-based resin designed for the fabrication of biocompatible, short term use, removable dental appliances by 3D printing. It is intended for 3D printing dental implant accessories such as dental surgical guides.
MDR classification	Class I by Annex VIII, Rule 5, 1st Paragraph, 2nd Indent
Notified Body	Not applicable — manufacturer self-certified under Class I
EU Authorized Representative	Not applicable
Medical Device Regulation Assessment Route	Article 19 after drawing up the technical documentation set out in Annexes II and III

Title: CEO

Signature:



Name: Vaidas Talačka

Place and Date: Kaunas, 2026 09 02

Annex I – Applicable Common Specifications

This present declaration is also in conformity with the following Common Specifications:

Common Specification	Description
N/A	Not Applicable

Annex II – Applicable Harmonized Standards

Standard	Description
EN ISO 13485:2016+A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021	Medical devices — Application of risk management to medical devices
EN ISO 10993-1:2025	Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
EN ISO 7405:2025	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 20417:2026	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021+A1:2025	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
EN ISO 17665:2024	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices

Annex III – Product listing

REF	Description / Name	EMDN Code
SGR-28-CLE-050	AmeraLabs SGR-28 resin, Clear, 500g	Q0102050199
SGR-28-CLE-100	AmeraLabs SGR-28 resin, Clear, 1kg	
SGR-28-CLE-500	AmeraLabs SGR-28 resin, Clear, 5kg	

Version History

Version	Compiled by	Date	Description
01	Aistė Simokaitienė	2026 09 02	First issue