EU DECLARATION OF CONFORMITY

CE

Name of product: **INOX**

Variant:
INOX: 2 ml, MEGA PACK (4 x 2 ml)

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

SRN (Single Registration Number):
PL-MF-000003211

Purpose and range of use:
Gel promoting complete polymerisation of dental composites

Medical device of class I, according to the rule 5 of Annex VIII MDR (EU) 2017/745. Evaluation of conformity was conducted following the procedure relating to Annex II and III Regulation (EU) 2017/745.

BASIC UDI-DI:
590755302INOXJ5

Standards used for conformity assessment:

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices.
EN ISO 14971:2019/ A11:2021	
ISO/TR 24971:2020	Medical devices – Guidance on the application of ISO 14971
EN ISO 10993	Biological evaluation of medical devices
EN ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
Ph. Eur. 11 2023	European Pharmacopoeia

Reference documents:

- Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- ACT of April 7, 2022 on medical devices

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

This declaration of conformity is issued under the sole responsibility of manufacturer.

Honorata Sołowiej,
Person responsible for regulatory compliance,
On behalf of Wojciech Pawłowski
Stalowa Wola

09.08.2023 Honorata Sołowiej

signature, company stamp, date

Person responsible
for regulatory compliance

Data aktualizacji: 08.08.2023/5

Honorata Sołowiej