EU DECLARATION OF CONFORMITY

CE

Name of product: **RUBBER-DAM**

Variants:
- GREEN
- BLUE
- BLACK

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:
Product RUBBER-DAM is dedicated for gingiva protection during dental treatments.

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:
590755302KOFERDAM3W

Common specifications:

EN ISO 14971:2012	Medical devices — Application of risk management to medical devices.
EN ISO 10993	Biological evaluation of medical devices
EN ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN 1041:2008+A1:2013	Information provided by the manufacturer of medical devices.
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.
Ph. Eur. 10 2020	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
- The Act of May 20, 2010 about medical devices with a changes

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

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
CERKAMED
WOJCIECH PAWŁOWSKI
ul. Kwiatkowskiego 1
37-450 STALOWA WOLA
tel./fax 15 842 35 85
www.cerkamed.pl NIP 865-204-87-70

.....24.11.2021.....
signature, company stamp, date

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