

# EU DECLARATION OF CONFORMITY



**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 14971:2019**

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. 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
- 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

Person responsible  
for regulatory compliance

*Honorata Sołowiej*

07.07.2022 *Honorata Sołowiej*  
signature, company stamp, date