

EU DECLARATION OF CONFORMITY



Name of product: RUBBER-DAM LIQUID

Variants:

RUBBER-DAM LIQUID: 1,2 ml, MEGA PACK (4 x 1,2 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:

Light-cured rubber-dam liquid is dedicated for: gingiva protection during dental treatments, sealing rubber dams.

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:

590755302KOFERDAMLIQ4F

Common specifications:

EN ISO 14971:2019

EN ISO 14971:2019/ A11:2021

ISO/TR 24971:2020

EN ISO 10993

EN ISO 7405:2018

EN ISO 20417:2021

EN ISO 15223-1:2021

Ph. Eur. 10 2020

Medical devices – Application of risk management to medical devices.

Medical devices – Guidance on the application of ISO 14971

Biological evaluation of medical devices

Dentistry – Evaluation of biocompatibility of medical devices used in dentistry

Medical devices – Information to be supplied by the manufacturer

Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
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