

# EU DECLARATION OF CONFORMITY



**Name of product:** PROTECTIVE PADS FOR A PATIENT

**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:**

Protective pads for a patient face prevent from face injuries and impurities coming on face that could happen as a result of fairly harmless mechanical conditions that occur during dental procedures.

Medical device of class I, according to the rule 1 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:**

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**Common specifications:**

<b>EN ISO 14971:2012</b>	Medical devices — Application of risk management to medical devices
<b>EN ISO 10993</b>	Biological evaluation of medical devices
<b>EN ISO 7405:2018</b>	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
<b>EN 1041:2008+A1:2013</b>	Information provided by the manufacturer of medical devices.
<b>EN ISO 15223-1:2016</b>	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements
<b>Ph. Eur. 10 2020</b>	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**  
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*Honorata Sołowiej* 04.11.2021  
signature, company stamp, date