

# EU DECLARATION OF CONFORMITY



**Name of product:** YELLOW PORCELAIN ETCH

**Variant:**

YELLOW PORCELAIN ETCH: 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:**

Product is used for porcelain etching during reparations of the dentures and as well as for etching of the porcelain veneers, crowns or inlays before their cementation.

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:**

590755302YELLPORETCR2

**Common specifications:**

<b>EN ISO 14971:2012</b>	Medical devices — Application of risk management to medical devices
<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**

WOJCIECH PAWŁOWSKI

ul. Kwiatkowskiego 1

37-450 STALOWA WOLA

tel./fax 15 842 35 85

www.cerkamed.pl

NIP 865-204-87-70



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signature, company stamp, date