

# EU DECLARATION OF CONFORMITY



**Name of product:** TCAdent

**Variant:**

**TCAdent:** 10ml

**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:**

Preparation for local cauterisation of mucous membranes

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:**

590755302TCADENTN3

**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**

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*Honorata Sołowiej* 24.11.2021

signature, company stamp, date