

# EU DECLARATION OF CONFORMITY



**Name of product: BTR PEN  
(BROKEN TOOL REMOVER PEN)**

**Manufacturer:**

Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski  
37-450 Stalowa Wola, ul. Kwiatkowskiego 1

**SRN (Single Registration Number):**

PL-MF-000003211

**Purpose and range of use:**

Dental tool for removing broken canal instruments.

Medical device of class I, according to the rule 6 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:**

590755302BTRPENJN

**Common specifications:**

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices.
EN ISO 14971:2019/ A11:2021	Medical devices – Guidance on the application of ISO 14971
ISO/TR 24971:2020	Biological evaluation of medical devices
EN ISO 10993	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 7405:2018	Medical devices – Information to be supplied by the manufacturer
EN ISO 20417:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 15223-1:2021	Dentistry - Medical devices for dentistry – Instruments
EN 1639:2009	European Pharmacopoeia
Ph. Eur. 10 2020	

**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

07.07.2022 ..... *Honorata Sołowiej* .....  
signature, company stamp, date