

## EC DECLARATION OF CONFORMITY

**Name of product:** ENDO-PREP GEL



**Variant:**

**ENDO-PREP GEL:** 2 ml, 5 ml, 10 ml

**Manufacturer:**

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

**Purpose and range of use:**

Gel for root canals preparation.

Medical device of class II a, according to the rule 6 of Annex IX MDD 93/42/ EEC  
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

**Reference documents:**

- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body  
CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering, nr ID 2409, Erdő utca 101, 2092, Budakeszi, Hungary.

Conformity of the product confirmed with certificate No 144731-18-02-18 valid until 2023-02-17.

**We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.**

Honorata Sołowiej,

Person responsible for regulatory compliance, [www.cerkamed.pl](http://www.cerkamed.pl)

On behalf of Wojciech Pawłowski

Stalowa Wola

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE

**CERKAMED**

**WOJCIECH PAWŁOWSKI**

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*Honorata Sołowiej*

*24.11.2021*

signature, company stamp, date