

EC DECLARATION OF CONFORMITY



Name of product: ENDO-PREP GEL

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

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, Gyár utca 2. H-2040, Budaörs, Hungary, 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.

Conformity of the product confirmed with certificate No 1444413-13-02-18 valid until 2018-02-17.

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

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
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signature, company stamp, date