EC DECLARATION OF CONFORMITY

Name of product: ENDO-PREP CREAM



Manufacturer:

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

Purpose and range of use: Cream 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.

PRZEDSIEBIORSTWO PRODUKCY JNO-HANDLOWE CERKAMED WOJCIECH PAWŁOWSKI ul. nwiatkowskiego 1 37-450 STALOWA WOLA tel/fax 15 842 35 85 2017 - 01***2 15 842 35 85

signature, company stamp, date