

EC 2

EC DECLARATION OF CONFORMITY



Name of product: CITRIC ACID 40%

Manufacturer:

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

Purpose and range of use:

Preparation used in root canal treatment for root canal rinsing.

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
CERKAMED
WOJCIECH PAWŁOWSKI
ul. Kwiatkowskiego 1
37-450 STAŁOWA WOLA
tel/fax 15 842 35 85
www.cerkamed.pl NIP 865-204-87-70

2017-01-24

signature, company stamp, date

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