

EC DECLARATION OF CONFORMITY

Name of product: CITRIC ACID 40%



Variant:

CITRIC ACID 40%: 200g, 400g

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
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,
On behalf of Wojciech Pawłowski
Stalowa Wola

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
CERKAMED
WOJCIECH PAWŁOWSKI
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tel./fax 15 842 35 85
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Wojciech Pawłowski 24.11.2021
signature, company stamp, date