

EC DECLARATION OF CONFORMITY

Name of product: ENDO-SOLUTION



Variants:

ENDO-SOLUTION: 50 ml, 120 ml, 200g

ENDO-SOLUTION PREMIUM: 120 ml

Manufacturer:

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

Purpose and range of use:

Solution for root canal widening. Product used for mechanical root canal 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,
On behalf of Wojciech Pawłowski
Stalowa Wola

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
CERKAMED
WOJCIECH PAWŁOWSKI
ul. Kwiatkowskiego 1
37-450 STAŁOWA WOLA
tel./fax 15 842 35 85
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signature, company stamp, date