

EC 2

EC DECLARATION OF CONFORMITY



2409

Name of product: ENDO - SOLUTION

Variants:

ENDO - SOLUTION — 3W
ENDO - SOLUTION PREMIUM

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

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

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2017-01-24

signature, company stamp, date

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