

EC DECLARATION OF CONFORMITY

Name of product: CANAL DETECTOR



2409

Variant:

CANAL DETECTOR: 2 ml

Manufacturer:

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

Purpose and range of use:

Root canal orifices indicator

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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signature, company stamp, date

24.11.2021