

## EC DECLARATION OF CONFORMITY

Name of product: RED DETECTOR



**Variant:**

RED DETECTOR: 2 ml

**Manufacturer:**

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

**Purpose and range of use:**

Caries detector

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**  
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*Honorata Sołowiej* 25.11.2021

signature, company stamp, date