EC DECLARATION OF CONFORMITY

CE 2409

Name of product: **BLUE ETCH**

Variants:

BLUE ETCH: 2 ml, 10 ml, 50 ml, MEGA PACK (3 x 10 ml), MONSTER PACK (10 x 2 ml)

BLUE ETCH FLOW: 2 ml, 10 ml, 50 ml, MONSTER PACK (10 x 2 ml)

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

Purpose and range of use:
Dental etchant used for etching dentine and enamel prior to composites, fissures and cavity seals.

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.

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
CERKAMED
WOJCIECH PAWŁOWSKI
ul. Kwiatkowskiego 1
37-450 STALOWA WOLA
tel./fax 15 842 35 85
www.cerkamed.pl NIP 865-204-87-70

Honorata Sołowiej,
Person responsible for regulatory compliance,
On behalf of Wojciech Pawłowski
Stalowa Wola

24.11.2021

signature, company stamp, date