EC DECLARATION OF CONFORMITY

CE

2409

Name of product:

ALUSTAT (10 g)
ALUSTAT GEL (5 ml, 10 ml, MEGA PACK 3 x 10 ml)
ALUSTAT FOAM (0,8 g, MEGA PACK 4 x 0,8 g)

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

Purpose and range of use:
Product intended for use in dental treatment to staunch slight gingival bleedings.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to Annex II MDD 93/42 / EEC excluding section 4.

Reference documents:

- Council Directive 93/42 / EEC of 14 June 1993 concerning medical devices with a changes 2007/47/ EC
- The Act of May 20, 2010. about medical devices with a changes
- Regulation of the Minister of Health of February 17, 2016 on essential requirements and conformity assessment procedures for medical devices

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 products, 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 STALOWA WOLA
tel./fax 15 842 35 85
www.cerkamed.pl NIP 865-204-87-70

24.11.2021

signature, company stamp, date