

EC DECLARATION OF CONFORMITY



1011

Name of product:

CANAL CLEAN (45ml)

Manufacturer:

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

Purpose and range of use:

Liquid is intended for use during dental treatment to rinse root canal. It accelerates drying of the root canal before filling.

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:

NEOEMKI National Medical Device Conformity Assessment and Certification LLC., nr ID 1011, Albert Flórián út 3/a. H - 1097 Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-03-31.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

Wojciech Pawłowski,
Owner,
Stalowa Wola

On behalf of CEO Wojciech Pawłowski

Honorata Sołowiej
Honorata Sołowiej

31.03.2021

signature, company stamp, date

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
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