

EC DECLARATION OF CONFORMITY



1011

Name of product:

GLUCO-CHEX 2% (200 g, 400 g)

GLUCO-CHEX 2% GEL (5 ml, 10 ml)

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 dentistry for rising and preparation of root canals.

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 products, 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

31.03.2021

signature, company stamp, date

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

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