EC DECLARATION OF CONFORMITY

Name of product: CHLORAXID 5,25%

Variants:

CHLORAXID 5.25% CHLORAXID 5,25% EXTRA CHLORAXID 5,25% GEL CHLORAXID 5,25% GEL EXTRA

Manufacturer:

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

Purpose and range of use:

Preparation used in dentistry for root canals rinsing. It cleans the root canal and removes smear layer.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.

Reference documents:

- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Notified body:

Evaluation of conformity was conducted with participation of the notified body EMKI 1011, 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.

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 2017 -01- 2 437-450 STALOWA WOLA tel/fax 15 842 35 85

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signature & company stamp, date

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