

EC 1

EC DECLARATION OF CONFORMITY

Name of product: MTA+

Variants: MTA+
Bio MTA+



Manufacturer:

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

Purpose and range of use:

Preparation used during dental treatment as material for filling and remineralization of root canals.

Medical device of class IIa, according to the rule 8 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.

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signature & company stamp, date

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