

EC DECLARATION OF CONFORMITY



2409

Name of basic product:

RAINBOW FLOW (1 g)

Variants:

YELLOW (1g)

ORANGE (1g)

PINK (1g)

PURPLE (1g)

BLUE (1g)

GREEN (1g)

WHITE (1g),

DENTINA(1g),

RED (1g)

SUPER SIX (6 x 1g): YELLOW, ORANGE, PINK, PURPLE, BLUE, GREEN

Manufacturer:

Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski

37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:

The light-curing flow composite product is intended for: filling of milk teeth and permanent teeth, pit and fissure sealing, marking of root canal orifices.

Medical device of class IIa, according to the rule 8 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 product with variants, 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

CERKAMED

WOJCIECH PAWŁOWSKI

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signature, company stamp, date