

EU DECLARATION OF CONFORMITY



Name of product: GUTTA PERCHA PLUGGER

Variants:

- size 0,6 mm
- size 0,8 mm
- size 1,0 mm
- size 1,2 mm

Manufacturer:

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

SRN (Single Registration Number):

PL-MF-000003211

Purpose and range of use:

Reusable dental instrument made of stainless steel for vertical condensation of gutta-percha.

Medical device of class I, according to the rule 6 of Annex VIII MDR (EU) 2017/745.

Evaluation of conformity was conducted following the procedure relating to Annex II and III Regulation (EU) 2017/745.

BASIC UDI-DI:

590755302GPPLUGGERTJ

Common specifications:

EN ISO 14971:2012

Medical devices — Application of risk management to medical devices

EN ISO 10993

Biological evaluation of medical devices

EN ISO 7405:2018

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

EN 1041:2008+A1:2013

Information provided by the manufacturer of medical devices.

EN ISO 15223-1:2016

Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EN 1639:2009

Dentistry - Medical devices for dentistry - Instruments

Ph. Eur. 10 2020

European Pharmacopoeia

Reference documents:

- Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- The Act of May 20, 2010 about medical devices with a changes

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

This declaration of conformity is issued under the sole responsibility of manufacturer.

Honorata Sołowiej,
Person responsible for regulatory compliance,
On behalf of Wojciech Pawłowski
Stalowa Wola

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
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Honorata Sołowiej
signature, company stamp, date

14.12.2024