



**CHEMA-ELEKTROMET**  
SPÓŁDZIELNIA PRACY

# EC DECLARATION OF CONFORMITY NO 106/1

**Manufacturer:** CHEMA-ELEKTROMET Spółdzielnia Pracy  
Przemysłowa 9, 35-105 Rzeszów, Poland  
Phone: +48 17 862 26 47, E-mail: chema@chema.rzeszow.pl

**The manufacturer declares that:**

1. Medical device: **CHEMASEAL**  
**Preparation for root canal filling and sealing**

- is classified as class III medical device according to classification rule 13 of Annex IX of Council Directive 93/42/EEC,
  - meets the Essential Requirements of the Council Directive 93/42/EEC and was subjected to the conformity assessment procedure as specified in Annex II of Council Directive 93/42/EEC implemented into Polish law, with the participation of Notified Body No. 1434, Polish Centre for Testing and Certification.
2. The manufacturer has implemented and maintains the Quality Management System according to the Standard PN-EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.

**This EC Declaration of conformity is issued under the sole responsibility of the manufacturer.**

**CE 1434**

**Vice President of the  
Management Board**

  
Jarosław Kalita

Rzeszów, 25.05.2021

**President of the  
Management Board**

  
Artur Ziomek