



**CHEMA-ELEKTROMET**  
SPÓŁDZIELNIA PRACY

# EC DECLARATION OF CONFORMITY NO 033/1

**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:

**AGATOS**

Type:

- **AGATOS S**  
Fast – setting phosphate cement
- **AGATOS W**  
Slow – setting phosphate cement

- is classified as class IIa medical device according to classification rule 8 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 (excluding section 4) of Council Directive 93/42/EEC implemented into Polish law, with the participation of Notified Body No. 1434, Polish Centre for Testing and Certification.
  - meets the requirements of the Standard PN-EN ISO 9917-1:2008 Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements.
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

**President of the  
Management Board**

  
Artur Ziomek

Rzeszów, 25.05.2021