



**CHEMA-ELEKTROMET**  
SPÓŁDZIELNIA PRACY

# EC DECLARATION

## OF CONFORMITY NO 049/1

**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: **ALUSTIN**  
**Stomatological haemostatic dressing**

- is classified as class I medical device according to classification rule 5 of Annex IX of Council Directive 93/42/EEC,
  - meets the Essential Requirements and other provisions of the Council Directive 93/42/EEC,
  - was subjected to the conformity assessment procedure as specified in Annex VII of Council Directive 93/42/EEC.
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**

**Vice President of the  
Management Board**

  
Jarosław Kalita

**President of the  
Management Board**

  
Artur Ziomek

Rzeszów, 25.05.2021