



CHEMA-ELEKTROMET
SPÓŁDZIELNIA PRACY

EC DECLARATION OF CONFORMITY NO 015/1

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:

CHEMA POLISH

- **CHEMA POLISH I**
Professional prophylaxis paste
- **CHEMA POLISH II**
Professional polishing paste

- 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.



**Vice President of the
Management Board**

Jarosław Kalita
Jarosław Kalita

**President of the
Management Board**

Artur Ziomek
Artur Ziomek

Rzeszów, 25.05.2021