



CHEMA-ELEKTROMET
SPÓŁDZIELNIA PRACY

EC DECLARATION

OF CONFORMITY NO 093/1

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:

ADHENAL PLUS

Denture adhesive cream

- 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