CHEMA-ELEKTROMET
SPÓŁDZIELNIA PRACY

EC DECLARATION

OF CONFORMITY NO 010/1

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: **PEROXIDON**

   Preparation for non-vital teeth bleaching

- is classified as class IIa medical device according to classification rule 7 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.

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