



**CHEMA-ELEKTROMET**  
SPÓŁDZIELNIA PRACY

# EU DECLARATION OF CONFORMITY NO 058/5

**Manufacturer:** CHEMA-ELEKTROMET Spółdzielnia Pracy  
Przemysłowa 9, 35-105 Rzeszów, Poland  
Phone: +48 17 862 26 47, E-mail: chema@chema.rzeszow.pl  
SRN: PL-MF-000010587

**The manufacturer declares that:**

1. Medical device: **WOSKI MODELOWE/MODELLING WAXES**  
Intended purpose: **Dental wax for making models of denture base plates**  
Type: **WOSK MODELOWY MIĘKKI/MODELLING WAX SOFT**  
**WOSK MODELOWY TWARDY/MODELLING WAX HARD**  
**WOSK MODELOWY TWARDY S/MODELLING WAX HARD S**

Basic UDI-DI: 590781148WoskiModeloweAE

- is classified as class I medical device according to classification rule 5 of Annex VIII Regulation (EU) 2017/745 of the European Parliament and of the Council,
  - is in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council,
  - meets the requirements of the European Standard EN ISO 15854:2023 Dentistry – Casting and baseplate waxes.
2. The manufacturer has implemented and maintains the Quality Management System according to the European Standard EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.

**This EU Declaration of conformity is issued under the sole responsibility of the manufacturer.**



**Vice President of the  
Management Board**

*Jarosław Kalita*

**President of the  
Management Board**

*Artur Ziomek*

**Rzeszów, 29.02.2024**