



# CERTIFICATE

**EC Certificate No. 1434-MDD-216/2021**  
**Full Quality Assurance System**  
**Directive 93/42/EEC concerning medical devices**

Polish Centre for Testing and Certification certifies  
that the quality assurance system in the organization:

**CHEMA-ELEKTROMET**  
**Spółdzielnia Pracy**  
**9 Przemysłowa Street**  
**35-105 Rzeszów, Poland**

for the design, manufacture and final inspection of  
medical devices, class IIa

## **Non-sterile dental products**

*The list of medical devices covered by this certificate is provided in the annex 1-2*

complies with requirements  
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 18.05.2021 to 27.05.2024

The date of issue of the Certificate: 18.05.2021



Issued under the Contract No. **MD-97/2020**  
Application No: **216/2020**  
Certificate bears the qualified signature.  
Warsaw, 18/05/2021  
Module **H2**

Anna  
Małgorzata  
Wyroba  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.19  
10:28:05 +02'00'  
**Vice-President**



## ANNEX 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No. 1434-MDD-216/2021**

*List of medical devices covered by the certificate:*

Commercial Name	Product version	Product features
EUGENOL	EUGENOL	Liquid for making ZnOE pastes
GUTAP	GUTAP	Gutta-percha solvent
GUTAP ORANGE (ENDOSTAR GUTTA CLEANER)	GUTAP ORANGE (ENDOSTAR GUTTA CLEANER)	Gutta-percha orange solvent
CITRIC ACID PLUS	CITRIC ACID PLUS	Root canal irrigation agent
MULTIDENTIN	MULTIDENTIN D	Temporary filling material
	MULTIDENTIN K	Temporary filling material
OXYDENTIN	OXYDENTIN	Temporary filling material
PEROXIDON	PEROXIDON	Preparation for non-vital teeth bleaching
PEROXIDON GEL	PEROXIDON GEL	Gel for non-vital teeth bleaching
PLASTIDENTIN	PLASTIDENTIN	Temporary filling material
PULPOGEL	PULPOGEL	Ferric sulfate gel for vital pulpotomy of primary teeth and bleeding control
THYMODENTIN	THYMODENTIN	Temporary filling material
ETCHANT	ETCHANT	Preparation for etching teeth enamel



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**Vice-President**

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.21  
13:53:27 +02'00'

/logotipas/

# SERTIFIKATAS

**CE Sertifikato Nr. 1434-MDD-216/2021**  
**Kokybės užtikrinimo sistema**  
**Medicinos Prietaisų Direktyva 93/42/EEC**

Lenkijos testavimo ir sertifikavimo centras patvirtina, kad kokybės užtikrinimo sistema organizacijoje:

**CHEMA – ELEKTROMET**  
**Spółdzielnia Pracy**  
**9 Przemysłowa Street**  
**35-105 Rzeszów, Lenkija**

Medicinių prietaisų, IIa klasės, gaminiui, dizaino kūrimui ir galutiniam patikrinimui

## **Nesterilūs odontologiniai produktai**

medicinių produktų sąrašas, kuriems taikomas CE sertifikatas, pateiktas priede 1-2

atitinka reikalavimus, pateiktus pagal Direktyvą 93/42/EEC Priedą II (išskyrus 4 skirsnį)  
priklausantį Lenkijos įstatymui, patvirtintam pagal PCPB auditą

Sertifikatas galioja: nuo 18.05.2021 iki 27.05.2024

Sertifikato išleidimo data: 18.05.2021



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Warsaw, 18/05/2021  
Module H2

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronizmie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.05.19  
10:28:05 +02'00'

**PRIEDAS 2 PRIE SERTIFIKATO  
GALIOJA TIK KARTU SU SERTIFIKATU  
Nr. 1434-MDD-216/2021**

Medicininiių produktų sąrašas, kuriems taikomas CE sertifikatas:

<b>Commercial Name</b>	<b>Product version</b>	<b>Product features</b>
EUGENOL	EUGENOL	Liquid for making ZnOE pastes
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