



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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Małgorzata Wyroba
Data: 2021.05.21
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/logotypas/

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
Spoldzielnia Pracy
9 Przemyslowa Street
35-105 Rzeszow, Lenkija

Mediciniųjų prietaisų, IIa klasės, gaminimui, 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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Anna
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Vice-President

Elektroniznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.05.19
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**PRIEDAS 2 PRIE SERTIFIKATO
GALIOJA TIK KARTU SU SERTIFIKATU
Nr. 1434-MDD-216/2021**

Medicininiių produktų sąrašas, kuriems taikomas CE sertifikatas:

Commercial Name	Product version	Product features
EUGENOL	EUGENOL	Liquid for making ZnOE pastes
GUTAP	GUTAP	Gutta-percha solvent
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