

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Przedsiębiorstwo Produkcyjno-Handlowe
CERKAMED Wojciech Pawłowski

Headquarters:

ul. Kwiatkowskiego 1, 37-450 Stalowa Wola, POLAND

Scope:

Medical devices for dentistry

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 36-CE-170822

Issue: 3

Issued: 06 April 2021

First issued: 18 February 2018

Start date of certified status: 18 February 2019

Expires:

17 February 2023

CE Certiso

Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.

H-2092 Budakeszi, Erdő u. 101.

Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager



The certificate covers the following devices:

Name of the device	Intended use	Risk class	Start date of certified status
BLUE ETCH	Dental etchant for dentine and enamel etching	II.a	18 February 2013
BLUE ETCH FLOW	Dental etchant for dentine and enamel etching	II.a	18 February 2013
CANAL DETECTOR	Root canal orifices indicator	II.a	18 February 2013
CHLORAXID 2%	Liquid for root canals rinsing	II.a	18 February 2013
CHLORAXID 2% EXTRA	Liquid for root canals rinsing	II.a	18 February 2013
CHLORAXID 2% GEL	Preparation for root canals rinsing	II.a	18 February 2013
CHLORAXID 2% GEL EXTRA	Preparation for root canals rinsing	II.a	18 February 2013
CITRIC ACID 40%	Liquid for root canals rinsing	II.a	18 February 2013
ENDO-SOLUTION	Liquid for root canals widening	II.a	18 February 2013
ENDO-SOLUTION PREMIUM	Liquid for root canals widening	II.a	18 February 2013
ENDO-PREP CREAM	Cream for root canals preparation	II.a	18 February 2013
ENDO-PREP GEL	Gel for root canals preparation	II.a	18 February 2013
EUCALYPTOL	Oil for gutta percha solving	II.a	18 February 2013
RED DETECTOR	Caries detector	II.a	18 February 2013
GUTTA PERCHA POINTS	Gutta percha points for root canals filling	II.a	18 February 2015
ABSORBENT PAPER POINTS	Paper points for root canals drying	II.a	18 February 2015

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H-2092 Budakeszi, Erdő u. 101.
Dr. Valtér PAPP
Zám: 23147049-2-13
General Manager

The certificate covers the following devices:

Name of the device	Intended use	Risk class	Start date of certified status
ALUSTAT	Liquid for staunching bleeding	II.a	06 April 2021
ALUSTAT FOAM	Foam for staunching bleeding	II.a	06 April 2021
ALUSTAT GEL	Gel for staunching bleeding	II.a	06 April 2021
BEST-CORD NANO	Impregnated retraction cords	II.a	06 April 2021
CALCIPAST	Calcium hydroxide paste for temporary root canal filling	II.a	06 April 2021
CAVIPACK	Product for temporary filling of cavities and for temporary sealing of root canal orifices	II.a	06 April 2021
CHLORAXID 5,25 %	Liquid for root canals rinsing	II.a	06 April 2021
CHLORAXID 5,25 % EXTRA	Liquid for root canals rinsing	II.a	06 April 2021
CHLORAXID 5,25 % GEL	Preparation for root canals rinsing	II.a	06 April 2021
CHLORAXID 5,25 % GEL EXTRA	Preparation for root canals rinsing	II.a	06 April 2021
ENDO-TOP	Endo irrigation needles	II.a	06 April 2021
EUGENOL	Oil for making pastes	II.a	06 April 2021
HYDROCAL	Calcium hydroxide cement for filling cavities	II.a	06 April 2021
MTA+	Material for filling and rebuilding of root canals	II.a	06 April 2021
BIO MTA+	Biomaterial for filling and rebuilding of root canals	II.a	06 April 2021
ORANGE GUTTANE	Oil for dissolving gutta-percha	II.a	06 April 2021
RAINBOW FLOW (WHITE, RED DENTINA, YELLOW, ORANGE, PINK, PURPLE, GREEN, BLUE)	Light-curing flow composite	II.a	06 April 2021

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Valter PAPP, Dr.
General Manager

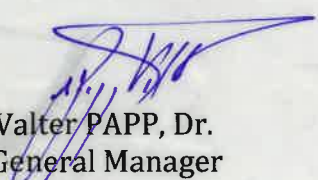


The certificate covers the following devices:

Name of the device	Intended use	Risk class	Start date of certified status
SYNTEX	Root canals filling and sealing material	II.a	06 April 2021
TOTAL BLEND DENTINA	Light-curing primer based on calcium hydroxide	II.a	06 April 2021
TOTAL BLEND WHITE	Light-curing primer based on calcium hydroxide	II.a	06 April 2021
TOTAL BLEND BLUE	Light-curing primer based on calcium hydroxide	II.a	06 April 2021
ZINC OXIDE	Material for making pastes	II.a	06 April 2021
ZINC OXIDE FAST	Fast-setting root canal repair material	II.a	06 April 2021

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Valter PAPP, Dr.
General Manager





PPH Cerkamed Wojciech Pawłowski
ul. Kwiatkowskiego 1
37-450 Stalowa Wola
Polska

Stalowa Wola, 21 March 2023

MANUFACTURER STATEMENT

According to the *REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* certificates issued by notified bodies in accordance with the Directive 90/385/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date 31.12.2028 (for IIa class devices), if before the date of expiry of the certificate, the manufacturer and a notified body have concluded a written agreement.

PPH Cerkamed Wojciech Pawłowski, hereby declares that fulfils the conditions necessary for certificate extension according to the *REGULATION (EU) 2023/607*.

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
CERKAMED
WOJCIECH PAWŁOWSKI
ul. Kwiatkowskiego 1
37-450 STAŁOWA WOLA
tel./fax 15 842 35 85
NIP 865-204-87-70 BDO 000068772

Person responsible
for regulatory compliance
Honorata Sołowiej
Honorata Sołowiej

.....
signature, company stamp, date

Reg.no.: K-2023/1

Subject: MDCG 2022-18 application

**Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów
Biobójczych**

Al. Jerozolimskie 181C

02-222 Warszawa

To whom it may concern,

The conformity assessment certificate of our client, **Przedsiębiorstwo Produkcyjno-Handlowe Cerkamed Wojciech Pawłowski** (address: ul. Kwiatkowskiego 1, 37-450 Stalowa Wola, Poland) will expire on 17 February 2023. The 144731-18-02-18 certificate was issued according to Annex II. excluding (4) of Annex II of the Medical Device Directive, the scope is "Medical devices for dentistry".

The organization submitted an application for conformity assessment to us, and the application was accepted. The contract between the parties was signed on 11 November 2022 by CE Certiso, on 21 November 2022 by P.P.H. Cerkamed.

The following products are included in the application (product name, Basic UDI-DI):

Zinc Oxide Fast, 590755302ZINCOXIDEZD

Gutta Percha Points, 590755302GPPOINTSBB

Endo-Top, 590755302ENDOTOPQ7

Absorbent paper point, 590755302AbsorbentPaperGG

Best-Cord nano, 590755302BESTCORDNANO4Y

Eugenol, 590755302EUGENOLQP

Zinc Oxide, 590755302ZINCOXIDEZD

Blue Etch, 590755302BLUEETCH2L

Blue Etch Flow, 590755302BLUEETCH2L

Citric Acid 40%, 590755302CITRICACID6J

Eucalyptol, 590755302EUCALYPTOLDM

Alustat, 590755302ALUSTATSW

Alustat Foam, 590755302ALUSTATFOAMFF

Alustat Gel, 590755302ALUSTATGELGP

Canal detector, 590755302CANALDETECTORFR

Red detector, 590755302REDDETECTORYP

Cavipack, 590755302CAVIPACKWN

Syntex, 590755302SYNTEXTN

RAINBOW FLOW, 590755302RAINBOWFLOW8Y

MTA+, 590755302MTA+FV

BIO MTA+, 590755302MTA+FV

ORANGE GUTTANE, 590755302ORANGEGUTTANEMJ

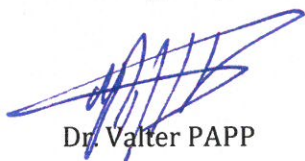
CE Certiso Kft started the conformity assessment process, namely the review of the technical documentations, the procedure is not finished yet. As long as the conformity assessment procedure is not finalized, we cannot declare that the devices would conform to the relevant MDR requirements.

The last audit of the organization was performed on 08-09 December 2021, one non-conformity was raised against the quality management system, namely against the lack of MDR Article 120(3) reference in the quality manual, the nonconformity was closed on 20 December 2021. No product quality or safety-related issue was identified during the audit. Based on the audit findings we can declare that the products of P.P.H. CerKamed do not present any unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

To ensure the application of Article 97 of the MDR we hereby commit ourselves to inform your Authority about any major safety-related shortcomings identified during conformity assessment, if any.

Budakeszi, 2023-01-06

Best regards,



Dr. Václav PAPP
General manager

Katowice, 05 April 2023

PPH CERKAMED Wojciech Pawłowski
ul. Kwiatkowskiego 1
37-450 Stalowa Wola
Poland

CONFIRMATION LETTER

To whom it may concern

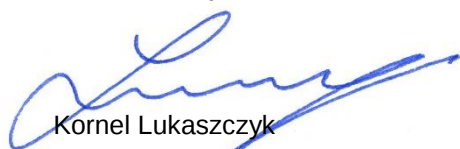
We confirm that PPH Cerkamed Wojciech Pawłowski submitted an application for conformity assessment acc. EU Reg. 2017/745 to TÜV Nord Polska Sp. z o.o. (NB 2274), and the application was accepted. The contract between the parties was signed on 16 February 2023, before expiry of the MDD certificate.

The following products are included in the application:

No	PRODUCT NAME	BASIC UDI-DI
1	CHLORAXID 2%	590755302CHLORAXID2%YB
2	ENDO-PREP CREAM	590755302ENDOPREPCREAMCM
3	ENDO-PREP GEL	590755302ENDOPREPGEL7E
4	CALCIPAST	590755302CALCIPAST8B
5	CHLORAXID 2% EXTRA	590755302CHLORAXID2%YB
6	CHLORAXID 5,25% EXTRA	590755302CHLORAXID5.25%WE
7	ENDO-SOLUTION	590755302ENDOSOLUTIONFG
8	CHLORAXID 5,25%	590755302CHLORAXID5.25%WE

Due to the above facts Medical Device Regulation (EU) 2017/745 Article 120 (2) applies as amended by the Regulation (EU) 2023/607.

Your sincerely



Kornel Lukaszczyk

Head of the Notified Body 2274

TÜV Nord Polska Sp. z o.o.

TÜV NORD Polska Sp. z o. o.

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40-085 Katowice
tel.: +48 32 786 46 46

biuro@tuv-nord.pl
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Kapitał zakładowy: 850000 PLN

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