

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
Előgőrző és Tanúsító Kft.

Erdő u. 101.
7049-2-13

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

Issue: 3
 Issued: 06 April 2021

CE Certiso
 és Kórháztechnikai
 Gyártó és Tanúsító Kft.
 Budakeszi, Erdő u. 101.
 Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
 Azonosítószám: 23147049-2-13

Vatter, PAPP, BÉRES
 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

Issue: 3
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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
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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Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

144731-18-02-18

CE SERTIFIKATAS

PILNA KOKYBĖS UŽTIKRINIMO SISTEMA

Direktyva 93/42/EEC medicinos priemonėms, Priedas II išskyrus (4)

CE Certiso Ltd. (NB 2409) užtikrina, kad toliau paminėto gamintojo kokybės valdymo sistema toliau išvardintiems produktams ir jų kategorijoms atitinka direktyvos nustatytus reikalavimus.

gamintojas:

**Przedsiębiorstwo Produkcyjno-Handlowe
CERKAMED Wojciech Pawlowski**

Centrinė būstinė: **ul.Kwiatkowskiego 1, 37-450 Stalowa Wola, LENKIJA**

sritis:

Medicininės priemonės odontologijai

Šis sertifikatas galioja tik su priedais, sėkmingo metinio audito atveju.

Susijusios audito ataskaitos ID numeris: 36-CE-170822

Išdavimas: **3**

Išduota: 6 d. Balandžio mėn. 2021 m. liepos 29 d.

Pirmas išdavimas: 18 d. Vasario mėn. 2018 m.

Patvirtinto sertifikato pradžios data: 18 d. Vasario mėn. 2019 m.

/antspaudas/

/parašas/

Valter PAPP, Dr.

Generalinis Vadovas

Galioja iki:

17 d. Vasario mėn. 2023 m.

CE Certiso Kft.

H-2092 Budakeszi, Erdo utca 101.

Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

NB ID numeris: 2409

Sertifikatas apima toliau išvardintus produktus:

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

Leidimas: 3

Išleistas: 06 d. Balandžio mėn. 2021 m.

Pirmasis leidimas: 2016-01-03

/antspaudas/

/parašas/

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NB ID numeris: 2409

Sertifikatas apima toliau išvardintus produktus:

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

Leidimas: 3

Išleistas: 06 d. Balandžio mėn. 2021 m.

Pirmasis leidimas: 2016-01-03

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NB ID numeris: 2409

Sertifikatas apima toliau išvardintus produktus:

Name of the device	Intended use	Risk class	Start date of certified status
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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

Leidimas: 3

Išleistas: 06 d. Balandžio mėn. 2021 m.

Pirmasis leidimas: 2016-01-03

/antspaudas/

/parašas/

Valter PAPP, Dr.

Generalinis Vadovas

CE Certiso Kft.

H-2092 Budakeszi, Erdo utca 101.

Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu

NB ID numeris: 2409



CE Certiso Kft.

Reg.no: K-2023/45

CONFIRMATION LETTER

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

The organization submitted an application for conformity assessment to CE Certiso Kft. (NB 2409), 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, **before the expiry of the MDD certificate**.

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

Zinc Oxide Fast	590755302ZINCOXIDEZD
Gutta Percha Points	590755302GPPPOINTSBB
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	590755302CAVIPACKWVN
Syntex	590755302SYNTEXTN
RAINBOW FLOW	590755302RAINBOWFLOW8Y
MTA+	590755302MTA+FV
BIO MTA+	590755302MTA+FV
ORANGE GUTTANE	590755302ORANGEGUTTANEMJ

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

Budakeszi, 20 March 2023

Dr. ~~Valter~~ PAPP
General Manager



PATVIRTINIMO LAIŠKAS

Mūsų kliento, Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawlowski (adresu: ul. Kwiatkowskiego 1, 37-450 Stalowa Wola, Lenkija) atitikties įvertinimo sertifikatas galiojantis iki 17d. Vasario mėn. 2023 m. Sertifikatas 144731-18-02-18 buvo išduotas pagal Medicinos prietaisų direktyvos (MDD) II Priedą, išskyrus 4 dalį, taikymo sritis yra „Mediciniai prietaisai odontologijai“.

Organizacija pateikė paraišką CE Certiso Kft. (NB 2409) atitikties įvertinimui, ir paraiška buvo priimta. Sutartis tarp šalių buvo pasirašyta 11d. Lapkričio mėn. 2022 m. CE Certiso, o 21d. Lapkričio mėn. 2022 m. P.P.H. Cerkamed, prieš pasibaigiant galioti MDD sertifikatui.

Į paraišką įtraukti šie produktai (produkto pavadinimas, pagrindinis 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	590755302REDEDETECTORYP
Cavipack	590755302CAVIPACKWN
Syntex	590755302SYNTEXTN
RAINBOW FLOW	590755302RAINBOWFLOW8Y
MTA+	590755302MTA+FV
BIO MTA+	590755302MTA+FV
ORANGE GUTTANE	590755302ORANGEGUTTANEMJ

Dėl aukščiau nurodytų faktų Medicinos prietaisų Reglamentas (ES) 2017/745 120 straipsnio 2 dalies a punktas taiko su pakeitimais, padarytais pagal Reglamentą (ES) 2023/607.

Budakeszi, 20 d. Kovo mėn. 2023 m.

/parašas/ /antspaudas/

Dr. Valter PAPP

Generalinis direktorius

www.cccertiso.hu

info@cccertiso.hu

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


Kornei Lukaszczyk

Head of the Notified Body 2274

TÜV Nord Polska Sp. z o.o.

TÜV NORD Polska Sp. z o. o.

ul. Mickiewicza 29
40-085 Katowice
tel.: +48 32 786 46 46

biuro@tuv-nord.pl
www.tuv-nord.pl

Zarząd:
Dagmara Żygowska - Prezes Zarządu

NIP 634-10-14-590
REGON: 272557766
Sąd Rejonowy w K-cach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:
mBank o. korporacyjny Katowice
02 1140 1078 0000 4042 4600 1001

Katowice, 05 Balandis 2023 m.

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

PATVIRTINIMO LAIŠKAS

Tiems, kam tai gali būti aktualu

Patvirtiname, kad PPH Cerkamed Wojciech Pawłowski pateikė paraišką atitikties įvertinimui pagal acc. ES Reg. 2017/745 į TÜV Nord Polska Sp. z o.o. (NB 2274), ir paraiška buvo priimta. Sutartis tarp šalių buvo pasirašyta 2023 m. vasario 16 d., nepasibaigus MDD pažymos galiojimo laikui.

Produktai, įtraukti į paraišką:

Nr	PRODUKTO PAVADINIMAS	PAGRINDINIS 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

Dėl aukščiau nurodytų faktų Medicinos prietaisų Reglamentas (ES) 2017/745 120 straipsnio 2 dalies a punktas taiko su pakeitimais, padarytais pagal Reglamentą (ES) 2023/607.

Nuoširdžiai,

/parašas/

Kornel Lukaszczyk

Notifikuotosios įstaigos 2274 vadovas

TÜV Nord Polska Sp. z o.o.

Dokumentą elektroniniu parašu

pasirašė

Data: 2025-03-06 10:29:10

Paskirtis: Pirkimo nr. 925806

Vieta: Energetikų g. 8, Kaunas

Kontaktinė informacija: Viešųjų

pirkimų specialistė