

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
Ellátó 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
Értékelési és Tanúsító Kft.
Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecetiso.hu / www.cecetiso.hu
Regisztrációs szám: 23147049-2-13

Váner PAPP, Dr.
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

Issued: 06 April 2021

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 |
|---------------------|--|------------|--------------------------------|
| 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 |

Issue: 3

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CE Certiso

Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
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/

Valter PAPP, Dr.

Generalinis Vadovas

CE Certiso Kft.

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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 |
|--|--|------------|--------------------------------|
| ALUSTAT | Liquid for staunching bleeding | II.a | 06 April 2021 |
| ALUSTAT FOAM | Foam for staunching bleeding | II.a | 06 April 2021 |
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| 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 |
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| 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

/antspaudas/

/parašas/

Valter PAPP, Dr.

Generalinis Vadovas

CE Certiso Kft.

H-2092 Budakeszi, Erdo utca 101.

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

NB ID numeris: 2409

Sertifikatas apima toliau išvardintus produktus:

| 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 |

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

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 | 590755302REDDETECTORYP |
| 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 Lukaszczuk

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