144731-18-02-18

EC CERTIFICATE

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

CE Certiso Ltd.
NB2409
Notified Body

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

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

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NB ID number: 2409

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

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H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

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NB ID number: 2409

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
Issued: 06 April 2021

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H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

CE Certiso Ltd. NB2409 Notified Body

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

Stalowa Wola, 21 March 2023

MANUFACTURER STATEMENT

Concerns: validity of EC Certificate No 144731–18–02-18

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 93/42/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 fulfilles the conditions necessary for certificate extension according to the *REGULATION (EU) 2023/607*, which is confirmed by enclosed Annexes 1 and 2.

Attached annexes:

Annex No. 1 - Confirmation letter PPH Cerkamed CE CERTISO MDR extension

Annex No. 2 - Confirmation letter PPH Cerkamed TUV NORD POLSKA MDR extension

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

Person responsible
for regulatory compliance
Honorata Sołowiej
Honorata Sołowiej
21.03.2023

signature, company stamp, date

CE Certiso Kft. – NB 2409

H-2092 Budakeszi, Erdő utca 101.

09 November 2023

Notified Body Confirmation Letter

Reference: K-2023/142

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2409 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski

ul. Kwiatkowskiego 1
37-450 Stalowa Wola
POLAND

SRN Number (if available): PL-MF-000003211

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the

applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

signed by: Dr. Valter Papp
CE Certiso KFT

Valter PAPP, dr.
General manager

CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **Zinc Oxide Fast** 590755302ZINCOXIDEZD	Class IIa, rule 7	N/A	144731-18-02-18 NB 2409
Device 2 **Gutta Percha points** 590755302GPPOINTSBB	Class IIa, rule 8	N/A	144731-18-02-18 NB 2409
Device 3 **Endo-Top** 590755302ENDOTOPQ7	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 4 **Absorbent paper point** 590755302AbsorbentPaperGG	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 5 **Best-Cord nano** 590755302BESTCORDNANO4Y	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 6 **Eugenol** 590755302EUGENOLQP	Class IIa, rule 7	N/A	144731-18-02-18 NB 2409
Device 7 **Zinc Oxide** 590755302ZINCOXIDEZD	Class IIa, rule 7	N/A	144731-18-02-18 NB 2409
Device 8 **Blue Etch** 590755302BLUEETCH2L	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 9 **Blue Etch Flow** 590755302BLUEETCH2L	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 10 **Citric Acid 40%** 590755302CITRICACID6J	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 11 **Eucalyptol** 590755302EUCALYPTOLDM	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 12 **Alustat** 590755302ALUSTATSW	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 13	Class IIa, rule 6	N/A	144731-18-02-18

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NB ID number: 2409

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Alustat Foam 590755302ALUSTATFOAMFF			NB 2409
Device 14 **Alustat Gel** 590755302ALUSTATGELGP	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 15 **Canal detector** 590755302CANALDETECTORFR	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 16 **Red detector** 590755302REDDETECTORYP	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 17 **Cavipack** 590755302CAVIPACKWN	Class IIa, rule 7	N/A	144731-18-02-18 NB 2409
Device 18 **Syntex** 590755302SYNTEXTN	Class IIa, rule 8	N/A	144731-18-02-18 NB 2409
Device 19 **MTA+** 590755302MTA+FV	Class IIa, rule 8	N/A	144731-18-02-18 NB 2409
Device 20 **BIOMTA+** 590755302MTA+FV	Class IIa, rule 8	N/A	144731-18-02-18 NB 2409
Device 21 **Orange guttane** 590755302ORANGEGUTTANEMJ	Class IIa, rule 6	N/A	144731-18-02-18 NB 2409
Device 22 **Rainbow Flow** 590755302RAINBOWFLOW8Y	Class IIa, rule 8	N/A	144731-18-02-18 NB 2409

CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
09-11-2023	K-2023/142	Initial issue
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CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

TÜVNORD

Katowice, 20 September 2023

Kornel Lukaszczyk
tel.kom. +48 693-620-824
k.lukaszczyk@tuv-nord.pl

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 one of conditions of the Regulation (EU) 2023/607 is met.

Your sincerely

Kornel Lukaszczyk
Head of the Notifed Body 2274
TÜV Nord Polska Sp. z o.o.