

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".

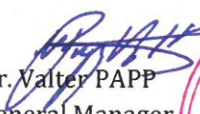
The organization submitted an application for conformity assessment to CE Certiso Kft. (NB 2409), and the application was accepted. The **contract between the parties was signed** on 11 November 2022 by CE Certiso, on 21 November 2022 by P.P.H. Cerkamed, **before the expiry of the MDD certificate**.

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	590755302CAVIPACKWN
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





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notified bodies in accordance with the Directive 90/385/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date 31.12.2028 (for IIa class devices), if before the date of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

Katowice, 05 April 2023

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

CONFIRMATION LETTER

To whom it may concern

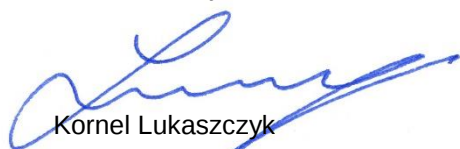
We confirm that PPH Cerkamed Wojciech Pawłowski submitted an application for conformity assessment acc. EU Reg. 2017/745 to TÜV Nord Polska Sp. z o.o. (NB 2274), and the application was accepted. The contract between the parties was signed on 16 February 2023, before expiry of the MDD certificate.

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.

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