

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

Issue: 3

Issued: 06 April 2021

CE Certiso
Orvosi és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
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

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

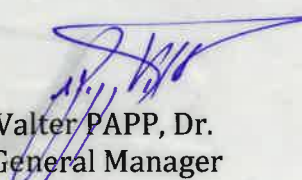


The certificate covers the following devices:

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
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

