EC DECLARATION OF CONFORMITY

CE
1011

Name of product: **GLUCO-CHEX 2%**

Variants:
- **GLUCO-CHEX 2%**: 200 g, 400 g
- **GLUCO-CHEX 2% GEL**: 5 ml, 10 ml

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:
Product intended for use in dentistry for rising and preparation of root canals.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:
- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body:
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság. National Institute of Pharmacy and Nutrition (EMKI), no. ID 1011, Zrínyi utca 3. H-1051, Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-01-02.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

under the authority
of the owner Wojciech Pawłowski:

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

International Sales Manager
Honorata Sołowiej

25.02.2018

.....
signature, company stamp, date

EC DECLARATION OF CONFORMITY

CE 2409

Name of product: **CITRIC ACID 40%**

Variant:

CITRIC ACID 40%: 200g, 400g

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1

Purpose and range of use:
Preparation used in root canal treatment for root canal rinsing.

Medical device of class II a, according to the rule 6 of Annex IX MDD 93/42/ EEC
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:

- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body
CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering, no. ID 2409, Gyár utca 2. H-2040, Budaörs, Hungary.

Conformity of the product confirmed with certificate No 144731-18-02-18 valid until 2023-02-17.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

under the authority
of the owner Wojciech Pawłowski:

PRZEDSIĘBIORSTWO PRODUKCYJNO-HANDLOWE
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www.cerkamed.pl NIP 865-204-87-78

15.02.2018

International Sales Manager
Honorata Sołowiej

.....
signature, company stamp, date

Last update:18.02.2018/5

EC DECLARATION OF CONFORMITY

CE
1011

Name of product: **ENDO-TOP**

Variant:
ENDO-TOP: 20 pieces, 50 pieces, 100 pieces

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:
Endo irrigation needles.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:

- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body:
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság. National Institute of Pharmacy and Nutrition (EMKI), no. ID 1011, Zrínyi utca 3. H-1051, Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-01-02.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

under the authority
of the owner Wojciech Pawłowski:

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International Sales Manager
Honorata Sołowiej

25.02.2019

signature, company stamp, date

EC DECLARATION OF CONFORMITY

CE

1011

Name of product: **CHLORAXID 5,25%**

Variants:
CHLORAXID 5,25%: 200 g, 400 g
CHLORAXID 5,25% EXTRA: 200 g, 400 g
CHLORAXID 5,25% GEL: 2 ml
CHLORAXID 5,25% GEL EXTRA: 2 ml

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:
Product for root canals rinsing. During mechanical canal widening it removes the non-vital pulp debris.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:
- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body:
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság. National Institute of Pharmacy and Nutrition (EMKI), no. ID 1011, Zrínyi utca 3. H-1051, Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-01-02.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

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International Sales Manager
Honorata Sołowiej

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25.02.2019

signature, company stamp, date

Last update: 18.02.2018/5

EC DECLARATION OF CONFORMITY

CE 2409

Name of product: **CHLORAXID 2%**

Variants:
CHLORAXID 2%: 200 g, 400 g
CHLORAXID 2% EXTRA: 200 g, 400 g
CHLORAXID 2% GEL: 2 ml
CHLORAXID 2% GEL EXTRA: 2 ml

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1

Purpose and range of use:
Product used in dentistry for root canal rinsing, cleans the canal and removes smear layer.

Medical device of class II a, according to the rule 6 of Annex IX MDD 93/42/ EEC
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:
- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body
CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering, no. ID 2409, Gyár utca 2. H-2040, Budaörs, Hungary.

Conformity of the product confirmed with certificate No 144731-18-02-18 valid until 2023-02-17.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

under the authority
of the owner Wojciech Pawłowski:

International Sales Manager
Honorata Sołowiej

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23.02.2018

signature, company stamp, date

Last update: 18.02.2018/6

EC DECLARATION OF CONFORMITY

CE
1011

Name of product: **CALCIPAST**

Variants:
- **CALCIPAST**: 2,1 g, MEGA PACK (4 x 2,1 g)
- **CALCIPAST+I**: 2,1 g, MEGA PACK (4 x 2,1 g)
- **CALCIPAST FORTE**: 2,1 g, MEGA PACK (4 x 2,1 g)

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:
Calcium hydroxide paste is intended for use in dental treatment as a material for temporary root canal filling.

Medical device of class IIa, according to the rule 7 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:
- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body:
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság. National Institute of Pharmacy and Nutrition (EMKI), no. ID 1011, Zrínyi utca 3. H-1051, Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-01-02.

We declare with full responsibility that the manufactured product, which this statement refers to, complies with the reference documents mentioned above.

under the authority
of the owner Wojciech Pawłowski:

International Sales Manager
Honorata Sołowiej

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25.02.2018 H. Sołowiej

signature, company stamp, date

EC DECLARATION OF CONFORMITY

CE 1011

Name of product: **ALUSTAT**

Variants:
- **ALUSTAT**: 10 g
- **ALUSTAT GEL**: 5 ml, 10 ml, MEGA PACK (3 x 10 ml)
- **ALUSTAT FOAM**: 0,8 g, MEGA PACK (4 x 0,8 g)

Manufacturer:
Przedsiębiorstwo Produkcyjno-Handlowe CERKAMED Wojciech Pawłowski
37-450 Stalowa Wola, ul. Kwiatkowskiego 1, POLAND

Purpose and range of use:
Preparation intended for use in dental treatment to staunch slight gingival bleedings.

Medical device of class IIa, according to the rule 6 of Annex IX MDD 93/42/ EEC.
Evaluation of conformity was conducted following the procedure relating to the EC Declaration of Conformity set out in Annex II excluding p.4 of Directive 93/42/EEC as amended 2007/47/EC.

Reference documents:
- MDD 93/42/ EEC as amended 2007/47/EC
- Annex I of MDD 93/42/EEC as amended 2007/47/EC

Evaluation of conformity was conducted with participation of the notified body:
Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság. National Institute of Pharmacy and Nutrition (EMKI), no. ID 1011, Zrínyi utca 3. H-1051, Budapest, Hungary.

Conformity of the product confirmed with certificate No 5-780-200-1601 valid until 2021-01-02.

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25.02.2018 H. Sołowiej

signature, company stamp, date

Last update: 18.02.2018/5