CERTYFIKAT WE / EC CERTIFICATE

zgodny z 93/42/EWG Załącznik II(b.p. 4) / *acc. 93/42/EEC Annex II(w.o. 4)*

Niniejszym zaświadcza się, że firma / *This certifies, that the company*

MEDISEPT Sp. z o.o.
ul. Konopnica 159c, PL / 21-030 Motycz

dla kategorii wyrobów klasy IIa i klasy IIb / *for the product category class IIa and class IIb*
(Lista wyrobów patrz załącznik 1 / *List of products see annex 1*)

Wyroby medyczne do dezynfekcji.

Medical devices for disinfection.

stosuje system zapewnienia jakości w projektowaniu, produkcji i kontroli końcowej wymienionych wyrobów zgodny z wymaganiami Załącznika II (z wyłączeniem sekcji 4) dyrektywy 93/42/EWG. Dodatkowo, przy znaku CE musi zostać naniesiony numer identyfikacyjny jednostki notyfikowanej. Ważność tego certyfikatu zależna jest od utrzymania systemu zapewnienia jakości zgodnego z wymaganiami dyrektywy i jego nadzorowania przez jednostkę notyfikowaną zgodnie z Załącznikiem II, rozdział 5. Certyfikat nie może być przenoszony pod żadnym warunkiem.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (excluding section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Nr rej. / *Reg.-No.* TNP/MDD/0306/4125/2020

Raport nr / Report No.: PL4125/2019-11_2

Ważny od / *Valid from* **17-02-2020**

Ważny do / *Valid until* **16-02-2023**

Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 17-02-2020

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29 40-085 Katowice

☎ +48 32 786 46 46, Fax +48 32 786 46 01
www.tuv-nord.pl, biuro@tuv-nord.pl

ZAŁĄCZNIK nr 1, strona 1 z 4 / ANNEX *No. 1, page 1 of 4*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0306/4125/2020**

Raport nr / Report No.: PL4125/2019-11_2

Ważny od / *Valid from* **17-02-2020**

Ważny do / *Valid until* **16-02-2023**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDN
Wyroby medyczne do dezynfekcji / *medical devices for disinfection*	Quatrodes Extra	IIa	16748
	DIRECT EXTRA SL	IIa	16748
	4-Des Extra	IIa	16748
	Quatrodes Forte	IIa	16748
	Dr. Mayer Hydra Forte	IIa	16748
	Quatrodes One	IIa	16748
	Quatro Basic	IIa	16748
	Saiko Max	IIa	16748
	Quatrodes Strong	IIa	16748
	Quatrodes Unit NF	IIa	16748
	DIRECT UNIT NF	IIa	16748
	Dr. Mayer AspiClear	IIa	16748
	Effective Suck NF	IIa	16748
	Saiko Suck	IIa	16748
	Saiko Wipes Premium	IIa	18776
	Velox Foam Extra	IIa	16748
	DIRECT FOAM EXTRA	IIa	16748
	Dr. Mayer Sonic Sensitive	IIa	16748
	Effective Sensitive Foam	IIa	16748
	Podoline Espuma desinfectante superficies	IIa	16748
	Saiko Foam	IIa	16748
	Alfi Foam Extra	IIa	16748
	Velox Foam Prim	IIa	16748
	Velox Foam	IIa	16748
	MEDISEPT Płyn do dezynfekcji zabawek rehabilitacyjnych	IIa	16748

Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 17-02-2020

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ZAŁĄCZNIK nr 1, strona 2 z 4 / ANNEX *No. 1, page 2 of 4*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0306/4125/2020**

Raport nr / Report No.: PL4125/2019-11_2

Ważny od / *Valid from* **17-02-2020**

Ważny do / *Valid until* **16-02-2023**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDN
Wyroby medyczne do dezynfekcji / *medical devices for disinfection*	Velox Rapid	IIa	16748
	Velox Spray lemon	IIa	16748
	Effective Spray lemon	IIa	16748
	Velox Spray neutral	IIa	16748
	BLUE CLEAN for surfaces neutral	IIa	16748
	Dr. Mayer Green Neutral	IIa	16748
	Medi Spray neutral	IIa	16748
	Effective Spray neutral	IIa	16748
	DIRECT SPRAY SL	IIa	16748
	Velox Spray tea tonic	IIa	16748
	Medi Spray tea tonic	IIa	16748
	Effective Spray tea tonic	IIa	16748
	Velodes Silk	IIa	16748
	Saiko Zid	IIa	16748
	DeviSept Spray Tea tonic	IIa	16748
	DIRECT SPRAY SL tea tonic	IIa	16748
	BLUE CLEAN for surfaces teatonic	IIa	16748
	Dr. Mayer Green Tonic	IIa	16748
	Velox Top AF grapefruit	IIa	16748
	Dr. Mayer Sonic grapefruit	IIa	16748
	Velox Top AF neutral	IIa	16748
	Podoline Spray desinfectante superficies	IIa	16748
	Dr. Mayer Sonic neutral	IIa	16748
	Velox Wipes	IIa	18776
	Effective Wipes Aroma	IIa	18776

Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 17-02-2020

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ZAŁĄCZNIK nr 1, strona 3 z 4 / ANNEX *No. 1, page 3 of 4*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0306/4125/2020**

Raport nr / Report No.: PL4125/2019-11_2

Ważny od / *Valid from* **17-02-2020**

Ważny do / *Valid until* **16-02-2023**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDN
Wyroby medyczne do dezynfekcji / *medical devices for disinfection*	Alsu Wipes	IIa	18776
	BLUE CLEAN wipes	IIa	18776
	DIRECT WIPES	IIa	18776
	Dr. Mayer Energy	IIa	18776
	Effective Wipes	IIa	18776
	Podoline Toallitas desinfectantes sin Alcohol	IIa	18776
	Saiko Wipes	IIa	18776
	Velox Wipes NA	IIa	18776
	Alfi Wipes	IIa	18776
	DIRECT WIPES NA	IIa	18776
	Dr. Mayer Energy Sensitive	IIa	18776
	Effective Wipes NO ALCOHOL	IIa	18776
	Viruton Bohr	IIb	16748
	DIRECT BOHR SL	IIb	16748
	Dr. Mayer Roth	IIb	16748
	Dril Safe	IIb	16748
	Effective Rotary	IIb	16748
	Podoline Desinfectante instrumental listo para usar	IIb	16748
	Saiko Drill	IIb	16748
	Viruton Extra	IIb	16748
	BLUE CLEAN for instruments	IIb	16748
	Dr. Mayer Ezo- Extreme	IIb	16748
	Effective Instru Extra	IIb	16748
	InsSept Extra	IIb	16748
	Podoline Desinfectante instrumental Plus	IIb	16748

Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 17-02-2020

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ZAŁĄCZNIK nr 1, strona 4 z 4 / ANNEX *No. 1, page 4 of 4*

do certyfikatu numer rejestracyjny / *to Certificate Registration No.:* **TNP/MDD/0306/4125/2020**

Raport nr / Report No.: PL4125/2019-11_2

Ważny od / *Valid from* **17-02-2020**

Ważny do / *Valid until* **16-02-2023**

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDN
Wyroby medyczne do dezynfekcji / *medical devices for disinfection*	Saiko Sept Extra	IIb	16748
	Viruton Foam	IIb	16748
	Viruton Forte	IIb	16748
	DIRECT FORTE SL	IIb	16748
	Dr. Mayer Ezo- Forte	IIb	16748
	Effective Instru	IIb	16748
	Podoline Desinfectante instrumental	IIb	16748
	Saiko Sept	IIb	16748
	Viruton Pre	IIb	16748
	Viruton Pulver	IIb	16748
	Dr. Mayer KeraSept	IIb	16748
	Effective Pulver	IIb	16748
	Saiko Sept Pulver	IIb	16748
	Viruton Strong	IIb	16748
	Velox Duo Wipes apple	IIa	18776
	Velox Duo Wipes neutral	IIa	18776
	Velox Duo Wipes tea tonic	IIa	18776
	MEDISEPT Chusteczki do dezynfekcji powierzchni	IIa	18776
	MEDISEPT Chusteczki do dezynfekcji rąk i powierzchni	IIa	18776
	MEDISEPT Spray do dezynfekcji butów do rehabilitacji	IIa	16748

Jowita Jużwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

Katowice, 17-02-2020

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PRESIDENT
of the Office for Registration of Medicinal Products,
Medical Devices and Biocidal Products

Warsaw, 20-02-2023

DNB.415.8.2023.1.MB

Medisept Sp. z o.o.
ul. Ludwika Spiessa 4
20-270 Lublin

In reference to your letter of 2 February 2023, informing that the CE certificate no. TNP/MDD/0306/4125/2020, issued to you as the manufacturer on 17 February 2020 by the notified body no. 2274 TUV Nord Polska Sp. z o. o., ul. Mickiewicza 29, 40-085 Katowice, and covering the following medical products for disinfection:

1. **Alfi Foam Extra**
2. **Alfi Wipes**
3. **BLUE CLEAN for surfaces neutral**
4. **BLUE CLEAN aspiration**
5. **BLUE CLEAN Duo wipes**
6. **BLUE CLEAN wipes for disinfection of hands and surfaces**
7. **BLUE CLEAN for instruments**
8. **BLUE CLEAN foam for surfaces**
9. **BLUE CLEAN cold**
10. **4-Des Extra**
11. **Dr. Mayer AspiClear**
12. **Dr. Mayer Ezo-Extreme**
13. **Dr. Mayer Ezo-Forte**
14. **Dr. Mayer Green Neutral**
15. **Dr. Mayer Green Tonic**
16. **Dr. Mayer Roth**
17. **Effective Suck NF**
18. **Effective Spray tea tonic**
19. **Effective Wipes**
20. **Effective Rotary**
21. **Effective Sensitive Foam**
22. **Effective Instru Extra**
23. **Effective Pulver**
24. **MEDISEPT Wipes for disinfection of hands and surfaces**
25. **Quatrodes Extra**

26. **Quatrodes Forte**
27. **Quatrodes One**
28. **Quatrodes Unit NF**
29. **Velox Foam Extra**
30. **Velox Spray neutral**
31. **Medi Spray neutral**
32. **Velox Spray tea tonic**
33. **Medi Spray tea tonic**
34. **Velodes Silk**
35. **DeviSept Spray Tea tonic**
36. **Velox Top AF grapefruit**
37. **Velox Top AF neutral**
38. **Velox Wipes**
39. **Alsu Wipes**
40. **Velox Wipes NA**
41. **Viruton Bohr**
42. **Dril Safe**
43. **Viruton Extra**
44. **InsSept Extra**
45. **Viruton Forte**
46. **Viruton Pre**
47. **Viruton Pulver**
48. **Dr. Mayer KeraSept**
49. **Velox Duo Wipes apple**
50. **Velox Duo Wipes neutral**
51. **Velox Duo Wipes tea tonic**
52. **Velox Oxy ETA**
53. **FrontER Etis-Sept**

expires as of 17 February 2023 and certification of the concerned products aimed at evidencing their conformity with requirements set by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Official Journal of the EU L 117 of 05.05.2017, p. 1, as amended, hereinafter referred to as Regulation (EU) 2017/745 has not been completed, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, rules as follows.

1. In accordance with art. 97 section 1 of the said Regulation (EU) 2017/745 *"Where, having performed an evaluation pursuant to Article 94, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the noncompliance."*
2. Considering the opinion of the Medical Device Coordination Group (MDCG) at the European Commission, included in the document MDCG 2022-18, as well as
3. Considering the following information obtained from you:

- documentation described in detail in the checklist in Attachment No. 1 hereto
- proof (letter of 27 January 2023 from the said notified body no. 2274) that you have initiated the procedure for evaluation of conformity of the said products by the said notified body and the agreement concluded with the said notified body on 26 January 2023.
- proof (letter of 27 January 2023 from the said notified body no. 2274) showing that the said notified body agreed to notify the President of the Office of any serious deficiencies revealed within the conformity assessment procedure which may be grounds for conviction that the product(s) may pose inacceptable threat to health and safety;

4. Based on the listed data and obtained documentation, as well as other available data, the President of the Office declares the following conclusions of the assessment according to art. 94 of the Regulation (EU) 2017/745:
   - from the date of expiry of the certificate no. TNP/MDD/0306/4125/2020 issued according to the Directive 93/42/CEE and without a valid certificate issued according to the Regulation (EU) 2017/745, the said medical products are not in conformity with the Regulation any more.
   - The said non-conforming products do not pose inacceptable threat to health and safety of patients, users and other persons or to other aspects of public health protection.
5. Therefore, based on art. 97 section 1 of the Regulation (EU) 2017/745, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products does not object to marketing and use of the said medical products for disinfection, covered by the certificate no. TNP/MDD/0306/4125/2020 issued in accordance with the Directive 93/42/CEE, until 16 February 2024, by which date the above found inconformity must be removed, provided that the manufacturer keeps the following conditions:
   - the manufacturer shall notify the President of the Office immediately of any delays in the conformity assessment procedure and will present reasonable grounds of such a delay;
   - the manufacturer (in accordance with art. 10 section 12 of the Regulation (EU) 2017/745) will notify all its distributors and, if needed, importers of the above inconformity and measures taken to remove it, including the above set deadline within which the manufacturer is obliged to ensure conformity of the said products with the said Regulation;
   - the product labelling, including the CE label will not be changed;
   - from 26 May 2021 and until removal of the inconformity, there have been no major changes to the products' structure and purpose;
   - the manufacturer shall notify the President of the Office immediately of issuing a certificate according to the Regulation (EU) 2017/745.
6. The manufacturer is hereby summoned by the President of the Office to remove the above inconformity by 16 February 2024 and informed that according to art. 50 section 4 of the act of 7 April 2022 on medical products (Journal of Laws of 2022, item 974) in the case referred to in art. 97 section 2 of the Regulation 2017/745, i.e. if the manufacturer fails to remove inconformity with binding requirements within the set deadline, the President of the Office shall issue an administrative decision concerning prohibition or limitation of market availability of the product, its withdrawal from market or use.
7. Further, the President of the Office reserves a right - in the case of obtaining significant information - to withdraw the non-opposition to market and use the said products within the set deadline, as expressed herein, or to change its scope.
8. The manufacturer is reminded that it is still obliged to observe provisions aimed at adapting medical products covered by temporary provisions contained in art. 120 which

are concerned in the present permit based on art. 97 of the Regulation (EU) 2017/745 with respect to surveillance and monitoring of the market, defined in Regulation (EU) no. 2017/745, and especially to requirements described in chapter VII section 2 of Regulation (EU) 2017/745 on surveillance. The manufacturer should also notify the President of the Office of any circumstances which may affect product safety.

9. Imposition of the measure described herein based on art. 97 section 1 of the Regulation (EU) 2017/745 does not release the products covered hereby or any entity related to their marketing and use from actions and obligations concerning market surveillance and monitoring, as those contemplated in art. 93 of the said Regulation.

10. The present measure expires in the case of issuing a new certificate(s) according to Regulation (EU) 2017/745 or prolongation of validity of the prior certificate no. TNP/MDD/0306/4125/2020 issued according Directive 93/42/CEE in line with the suggested amendment of art. 120 section 2 of the Regulation (EU) 2017/745.

To obtain further information on the issue in question, please contact the President of the Office quoting the reference no. of the present letter.

authorised by the President,

Sebastian Migdalski

Vice-President for Medical Devices

/document was signed electronically/

Attachments:

1. checklist

MEDISEPT
Perfect disinfection

Lublin, 7th April 2023

STATEMENT

MEDISEPT Sp. z o.o. located in ul. Ludwika Spiessa 4, 20-270 Lublin as manufacturer of medical devices hereby declares, that as a manufacturer producing products in accordance with ISO 13485 and Regulation 2017/745, the certificate in accordance with Directive 93/42/EEC based on the extension of Regulation 2017/745 is valid until on December 31st, 2028.

As a manufacturer, we have met all the requirements that allow us to extend the certificate issued in accordance with Directive 93/42/EEC:

1. MEDISEPT company has had confirmation of date of the first certification phase and has had signed contract for certification. We want to inform we are after first phase of certification which has placed on 15th February 2023 according to new legal requirements.
2. All medical devices produced by MEDISEPT company are made according to QMS adapted to new legal requirements. QMS was prepared according to requirements mentioned in MDR Regulation, including Article 120 and 83 of MDR Regulation.
3. As a manufacturer we declare we will not make and did not make changes in ingredients or filed of use in our products and did not make significant changes in products' presentations.
4. Application concerns only products listed on MDD certificate and transfer to MDR application. For mentioned products the certificate issued in accordance with the 93/42/EEC has not been suspended or withdrawn by notified body.

Thus, we can declare that the medical devices we produce can still be placed on the market under Directive 93/42/EEC until December 31, 2028.

The List of Medical Devices is attached to this letter.

V-ce President

Waldemar Ferschke

MEDISEPT Sp. z o.o.
ul. Ludwika Spiessa 4, Poland
Lublin, 20-270

Contact: phone.: +48 81 535 22 20
info@medisept.pl
www.medisept.pl

Medical Device List

- Viruton Forte;
- Dr. Mayer Ezo-Forte;
- Viruton Extra,
- BLUE CLEAN for intruments,
- Effective Instru Extra,
- InsSept Extra,
- Dr. Mayer Ezo-Extreme
- Viruton Pre
- Viruton Bohr,
- Dr. Mayer Roth,
- Dril Safe,
- Effective Rotary
-Viruton Pulver,
-Dr. Mayer KeraSept,
-Effective Pulver,
- Quatrodes Forte;
- Quatrodes Extra,
- 4-Des Extra,
- Effective Surface Extra
- Quatrodes One
- Quatrodes Unit NF,
- Effective Suck NF,
- Dr. Mayer Aspi-Clear,
- Velox Duo Wipes,
- Dr. Mayer Green Servetele;
- Velox Oxy ETA,
- FrontER Etis-Sept,
- Effective Oxy S;
- Velox Spray tea tonic,
- DeviSept Spray Tea tonic,
- Effective Spray tea tonic,
- Medi Spray tea tonic,
- Velodes Silk,
- Dr. Mayer Green Tonic
- Velox Spray neutral,
- Medi Spray neutral,
- Dr. Mayer Green Neutral,
- BLUE CLEAN for surfaces neutral;
- MEDISEPT Chusteczki do dezynfekcji rąk i powierzchni,
- Velox Top AF grapefruit
- Velox Top AF neutral
- Velox Wipes,
- Effective Wipes,
- Alsu Wipes
- Velox Foam Extra,
- Alfi Foam Extra,
- Effective Sensitive Foam
- Velox Wipes NA
- Alfi Wipes