MEDISEPT
Perfect disinfection

Lublin, 13th March 2023

STATEMENT

The company MEDISEPT Sp. z o.o. located on Ludwik Spiess 4 Street, 20-270 Lublin, Poland, as the manufacturer of the biocidal products hereby declares that according to:

REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 May 2012 concerning the making available on the market and use of biocidal products

and **Article 52:**

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the disposal, making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the disposal and use of existing stocks of the biocidal products concerned.

Biocidal products could be available 180 days after the expiry date of authorisation.

Edyta Klepcarz

Product Development Specialist

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ul. Ludwika Spiessa 4, Poland
Lublin, 20-270

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MEDISEPT
Perfect disinfection

Lublin, 13th January 2023

STATEMENT

MEDISEPT Sp.z.o.o., located in Ludwika Spiessa 4 Street, 20-270 Lublin, Poland, as manufacturer of medical devices dedicated for cleaning and disinfection hereby declares that according to Regulation (EU) 2017/745 medical devices could be lawfully placed on the market till 26th May 2024 by distributors.

Edyta Klepcarz

Edyta Klepcarz

MEDISEPT Sp. z o.o.
UL. LUDWIKA SPIESSA 4
20-270 LUBLIN
NIP: 946-00-10-016 R: 430566102

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MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI
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MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
INTRARE Nr. 300809/E
IEȘIRE
Ziua 07 Luna 03 Anul 2023

To:

MEDISEPT Sp. zo.o. ul. Ludwika Spiessa 4 Street, 20-270 Lublin, Poland
E-mail: info@medisept.pl

In response to the request made in your behalf by Mrs. Mihaela Epure (office@ chemconsult.ro) registered at the National Agency for Medicines and Medical Devices in Romania (ANMDMR) with number 300809/07.02.2023 (initial information) and 300809/24.02.2023 (submittance of documents) , we are communicating the following:

National Agency for Medicines and Medical Devices in Romania (ANMDMR) has been made aware of authorisation issued by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products for Medisept Sp. Zo.o., cu sediul în ul. Ludwika Spiessa 4, 20-270 Lublin, in accordance with art. 97 of Regulation (EU) 2017/745 for allowing further placing on the market medical products for desinfection manufactured by MEDISEPT ref. no. DNB.415.8.2023.1MB from 20th February 2023.

Based on the authorisations granted by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and taking into account the documents submitted along to the e-mail no. 300809/24.02.2023, the medical products for desinfection may be also placed on the Romanian market in the conditions stipulated in the document DNB.415.8.2023.1MB.

Having regard that the permission cease at the issuance of the certificate according MDR, MEDISEPT Sp. zo.o. is requested to inform also ANMDMR in this respect.

MEDISEPT Sp. zo.o. is requested to keep an evidence of the batches of products delivered in Romania under these conditions and to put at disposal of ANMDMR on demand.

ANMDMR reserves the rights to verify the compliance to the above mentioned conditions during the market surveillance actions on the Romanian market.

Best regards,

VICEPRESIDENT
Ioana TENE

MINISTERUL SĂNĂTĂȚII
AGENȚIA NAȚIONALĂ A MEDICAMENTULUI ȘI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA
PREȘEDINTE

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