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, IIb / *for the product category class IIa, 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.*: PL4125/2021-02

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

Katowice, 19-05-2021

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 5 / ANNEX *No. 1, page 1 of 5*

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

Raport nr / *Report No.*: PL4125/2021-02

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

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

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Wyroby medyczne do dezynfekcji / *Medical devices for disinfection*	MEDISEPT Chusteczki do dezynfekcji powierzchni / MEDISEPT Surface disinfectant wipes	IIa	18776
	MEDISEPT Chusteczki do dezynfekcji rąk i powierzchni / MEDISEPT Wipes for disinfecting hands and surfaces	IIa	18776
	Saiko Wipes Premium / Saiko Wipes Premium	IIa	18776
	MEDISEPT Spray do dezynfekcji butów do rehabilitacji / MEDISEPT Spray for disinfecting rehabilitation shoes	IIa	16748
	Quatrodes Extra / Quatrodes Extra	IIa	16748
		IIa	16748
		IIa	16748
	Quatrodes Forte / Quatrodes Forte	IIa	16748
		IIa	16748
	Quatrodes One	IIa	16748
		IIa	16748
		IIa	16748
	Quatrodes Unit NF	IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
	Velox Foam Extra	IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748

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

Katowice, 19-05-2021

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

Raport nr / *Report No.:* PL4125/2021-02

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

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

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Wyroby medyczne do dezynfekcji / *Medical devices for disinfection*		IIa	16748
	Velox Foam Prim	IIa	16748
	Velox Foam	IIa	16748
	MEDISEPT Płyn do dezynfekcji zabawek rehabilitacyjnych / MEDISEPT Disinfecting liquid for rehabilitation toys	IIa	16748
	Velox Rapid	IIa	16748
	Velox Spray lemon	IIa	16748
		IIa	16748
	Velox Spray neutral	IIa	16748
		IIa	16748
		IIa	16748
	Medi Spray neutral	IIa	16748
		IIa	16748
		IIa	16748
	Velox Spray tea tonic	IIa	16748
	Medi Spray tea tonic	IIa	16748
		IIa	16748
	Velodes Silk	IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
		IIa	16748
	Velox Top AF grapefruit	IIa	16748

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

Katowice, 19-05-2021

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

Raport nr / *Report No.:* PL4125/2021-02

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

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

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Wyroby medyczne do dezynfekcji / *Medical devices for disinfection*		IIa	16748
	Velox Top AF neutral	IIa	16748
	Pod[illegible]lar	IIa	16748
		IIa	16748
	Velox Wipes	IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
	Velox Wipes NA	IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
		IIa	18776
	Viruton Bohr	IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748

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

Katowice, 19-05-2021

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

Raport nr / *Report No.*: PL4125/2021-02

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

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

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Wyroby medyczne do dezynfekcji / *Medical devices for disinfection*		IIb	16748
		IIb	16748
	Viruton Extra	IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
	Viruton Foam	IIb	16748
	Viruton Forte	IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
	Viruton Pre	IIb	16748
	Viruton Pulver	IIb	16748
		IIb	16748
		IIb	16748
		IIb	16748
	Velox Duo Wipes apple	IIa	18776
	Velox Duo Wipes neutral	IIa	18776

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

Katowice, 19-05-2021

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

Raport nr / *Report No.*: PL4125/2021-02

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

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

Typ / *Type*	Wyroby / *Products*	Klasa / *Class*	UMDNS
Wyroby medyczne do dezynfekcji / *Medical devices for disinfection*	Velox Duo Wipes tea tonic	IIa	18776
	Velox Oxy ETA	IIa	16748
		IIa	16748
		IIa	16748
	Velox Maxx	IIa	16748
		IIa	16748
	Velodes Wipes	IIa	18776
	Quatrodes Ultra	IIa	16748
	Quatrodes Big	IIa	16748
		IIa	16748

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

Katowice, 19-05-2021

Jednostka notyfikowana Numer identyfikacyjny 2274
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TÜVNORD

Katowice, 15.02.2024

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

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

Notified Body Confirmation Letter
Reference: 1/24

To whom it may concern

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, TÜV NORD Polska Sp. z o.o., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2274 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDISEPT Sp. z o. o.
Ludwika Spiessa 4
20-270 Lublin
Poland
SRN: PL-MF-000032562

The devices covered by the formal application and the written agreement mentioned above are identified in the Table 1. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607) is 31 December 2028.

TÜVNORD

On behalf of the Notified Body,

Jowita Dyrda
Deputy Head of the Notifed Body No. 2274 for Medical Devices
TÜV Nord Polska Sp. z o.o.

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dr. Mayer KeraSept	Class IIb	N/A	Certificate: TNP/MDD/0306/4125/2020 NB: 2274
Effective Pulver	Class IIb	N/A	
Viruton Pulver	Class IIb	N/A	
Viruton Pre	Class IIb	N/A	
Dr. Mayer Ezo-Forte	Class IIb	N/A	
Viruton Forte	Class IIb	N/A	
BLUE CLEAN for intruments	Class IIb	N/A	
Dr. Mayer Ezo-Extreme	Class IIb	N/A	
Effective Instru Extra	Class IIb	N/A	
InsSept Extra	Class IIb	N/A	
Viruton Extra	Class IIb	N/A	
Dr. Mayer Roth	Class IIb	N/A	
Dril Safe	Class IIb	N/A	
Effective Rotary	Class IIb	N/A	
Viruton Bohr	Class IIb	N/A	
Velox Wipes NA	Class IIa	N/A	Certificate: TNP/MDD/0306/4125/2020 NB: 2274
Alfi Wipes	Class IIa	N/A	
Effective Wipes	Class lia	N/A	
Velox Wipes	Class IIa	N/A	
Alsu Wipes	Class IIa	N/A	
Velox Top AF neutral	Class IIa	N/A	
Velox Top AF grapefruit	Class IIa	N/A	
DeviSept Spray Tea tonic	Class IIa	N/A	
Dr. Mayer Green Tonic	Class IIa	N/A	
Effective Spray tea tonic	Class IIa	N/A	
Medi Spray tea tonic	Class IIa	N/A	
Velodes Silk	Class IIa	N/A	
Velox Spray tea tonic	Class lia	N/A	
BLUE CLEAN for surfaces neutral	Class IIa	N/A	
Dr. Mayer Green Neutral	Class IIa	N/A	
Medi Spray neutral	Class IIa	N/A	
Velox Spray neutral	Class IIa	N/A	

TÜV NORD Polska Sp. z o. o.

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Zarząd:
Dagmara Żygowska - Prezes Zarządu

NIP 634-10-14-590
REGON: 272557766
Sąd Rejonowy w Katowicach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:
mBank o. korporacyjny Katowice
02 1140 1078 0000 4042 4600 1001
EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Velox Duo Wipes	Class IIa	Velox Duo Vipes Tea Tonic	
Alfi Foam Extra	Class IIa	N/A	
Effective Sensitive Foam	Class IIa	N/A	
Velox Foam Extra	Class IIa	N/A	
Dr. Mayer Aspi-Clear	Class IIa	N/A	
Effective Suck NF	Class IIa	N/A	
Quatrodes Unit NF	Class IIa	N/A	
Quatrodes One	Class IIa	N/A	
Quatrodes Forte	Class IIa	N/A	
4-Des Extra	Class IIa	N/A	
Quatrodes Extra	Class IIa	N/A	
MEDISEPT Wipes for disinfecting hands and surfaces	Class IIa	N/A	
FrontER Etis-Sept	Class IIa	N/A	
Velox Oxy ETA	Class IIa	N/A	

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
15.02.2024	Version 1	Initial issue

TÜV NORD Polska Sp. z o. o.

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Zarząd:
Dagmara Żygowska - Prezes Zarządu

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REGON: 272557766
Sąd Rejonowy w Katowicach, KRS: 0000118633
Kapitał zakładowy: 850000 PLN

Konto bankowe:
mBank o. korporacyjny Katowice
02 1140 1078 0000 4042 4600 1001
EUR 72 1140 1078 0000 4042 4600 1002
USD 93 1140 1078 0000 4042 4600 1012

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

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