EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on MEDICAL DEVICES, Annex II excluding (4)

The certificate : **19M00099CRT03**

issued by:

DARE!! Services B.V.
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

to:

Manufacturer : MediTop BV
Address : Vlasakker 22
3417 XT Montfoort
The Netherlands

regarding the product categories ENT treatment devices and wound suction devices.
and grants the right to use the EC Notified Body Identification Number as represented below to accompany the CE Marking on the product(s) meeting the provisions of the EC Directive which apply to these product(s).

1912

This certificate is based on the following documents:
19M00099RPT01 (audit)
19M00125RPT01 (TD review)

DARE!! Services B.V. hereby declares that it has audited the quality system in accordance with MDD Annex II and that the relevant provisions of the Directive 93/42/EEC dated June 14, 1993 concerning Medical Devices, including all subsequent amendments and transposed into Dutch legislation under the name “Besluit Medische Hulpmiddelen” are fulfilled.
The validity of this certificate includes the surveillance obligations of Annex II, section 5.

Issued for the first time: **4-6-2020**
Reissued: **NA**
Valid to: **May 27, 2024 (Article 120, EU 2017/745)**

DARE!! Services B.V.

Dr.ir. W. Sjoerdsma
Certification decision maker

Ing. D. van der Vlugt
Director

Certificate number: 19M00099CRT03

Annex to EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on MEDICAL DEVICES, Annex II excluding (4)

The certificate : **19M00099CRT03**

Manufacturer : MediTop BV
Address : Vlasakker 22
3417 XT Montfoort
The Netherlands

Device	**Class**	**Marketed under tradename Entermed**
Aquatop	IIa	Enthermo III
ENT Treatment system	IIa	Entermed ENT treatment systems: - Futurent III - Futurent III microscopy - Futurent Ergo - Futurent Ergo microscopy - Micronomic III
Cautery transformer	IIa	Entermed cautery transformer
Exsudex XL	IIa	N.A.
Exsudex XS	IIa	N.A.

Additional sites:

Site : NA
Address : NA

Kiwa Dare

Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

Tel. +31 348 200 900
www.dare.nl
medcert@dare.nl

Supplement to EU CERTIFICATE

This supplement belongs to:
The certificate : 19M00099CRT03

issued by:	Kiwa Dare B.V. Vijzelmolenlaan 7 3447 GX Woerden The Netherlands	**to:**	Manufacturer Address Single Registration Number	MediTop BV Vlasakker 22 3417 XT Montfoort The Netherlands NA

And is based on the notification of the customer of discontinuation of the Cautery Transformer as described in the Addendum report.

The addendum report : 19M00099ADD02

The change encompasses the removal of the Cautery Transformer, Class IIa, from the certificate. As it is not allowed to issue a new or changed certificate under Directive 93/42/EEC from 26th May 2021, this supplement is issued.

Issued for the first time: **28-2-2022**
Reissued: **NA**
Valid to: **May 27, 2024**

Kiwa Dare B.V.

W. Sjoerdsma
Certification decision maker

D. van der Vlugt
Director

By Royal Charter

Supplementary information to AR120 811189

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

MediTop BV
Vlasakker 22
3417 XT Montfoort
The Netherlands

Date: 12 July 2024

Changes Approved:

Date	Reference Number	Action
12 July 2024	30200804	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Aquatop (Enthermo III), ENT Treatment system (Entermed ENT treatment systems: Futurent III, Futurent III microscopy, Futurent Ergo, Futurent Ergo microscopy, Micronomic III), Exsudex XL, Exsudex XS. Original NB Certificate Number: 19M00099CRT03.

Inspiring trust for a more resilient world.

12 July 2024

MediTop BV
Vlasakker 22
3417 XT Montfoort
The Netherlands

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
19M00099CRT03	AR120 811189	93/42/EEC Annex II excluding Section 4	30200804	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Aquatop (Enthermo III), ENT Treatment system (Entermed ENT treatment systems: Futurent III, Futurent III microscopy, Futurent Ergo, Futurent Ergo microscopy, Micronomic III), Exsudex XL, Exsudex XS. Original NB Certificate Number: 19M00099CRT03.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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