

DARE!! Medical Certifications

Medical certification services

Vijzelmolenlaan 7 3447 GX Woerden The Netherlands Tel. +31 348 430 979 www.dare.nl medcert@dare.nl

EC CERTIFICATE

Full Quality Assurance System Directive 93/42/EEC on MEDICAL DEVICES, Annex II excluding (4)

The certificate : 19M00099CRT02

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: 19M00099CRT02



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Annex to EC Certificate

Full Quality Assurance System Directive 93/42/EEC on MEDICAL DEVICES, Annex II excluding (4)

The certificate : 19M00099CRT02

Manufacturer : MediTop BV Address : Vlasakker 22

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Device	Class
Aquatop	lla
ENT Treatment system	lla
Cautery transformer	lla
Exsudex XL	lla
Exsudex XS	lla

Additional sites:

Site : NA Address : NA

Certificate number: 19M00099CRT02



Eori-number: NL805613468 VAT number: NL8056.13.468.B01