

Rutherford 11, 6422 RE Heerlen, The Netherlands

This is a multi-site certificate. Additional site details are listed in the appendix to this certificate.

Bureau Veritas Certification Denmark A/S certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below.

Standard

EN ISO 13485:2016

Scope of certification

Design & development, production, storage, sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.

Design & development, production, storage, sales and distribution of medical devices for donning, doffing and movement aids.

Original cycle start date:

12-December-2019

Expiry date of previous cycle:

NA

Certification/Recertification Audit date:

NA

Certification/ Recertification cycle start date:

12-December-2022

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: 11-December-2025

Certificate No.: DNKFRC102226 Version: 2 Revision date: 01-December-2022

Certification Office:

hily Absalonsen

Bureau Veritas Certification Denmark A/S Oldenborggade 25-31, 7000 Fredericia, Denmark

Further clarifications regarding the scope of this certificate and the applicability of the Management System requirements may be obtained by consulting the organization. To check this certificate validity, please call (+45) 77 311 000. 1/4







Standard

EN ISO 13485:2016

Scope of certification

Design & development, production, storage, sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients

Design & development, production, storage, sales and distribution of medical devices for donning, doffing and movement aids.

Site Name/location:	Site Addition Date:	Site Address:	Site Scope:
Arion Holding B.V. (Head Office)	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Design & development, production storage, sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients Design & development, production, storage, sales and distribution of medical devices for donning, doffing and movement aids.
Arion Manufacturing BV	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Design & development, production of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.

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Standard

EN ISO 13485:2016

Scope of certification

Site Name/location:	Site Addition Date:	Site Address:	Site Scope:
Arion International BV	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Storage, sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.
Arion Slide Solutions BV	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Design & development, production storage, sales and distribution of medical devices for donning, doffing and movement aids.
Arion Bathing '21 International BV	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.
Arion Nederland BV	12-December- 2019	Rutherford 11, 6422 RE Heerlen, The Netherlands	Sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.

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Standard

EN ISO 13485:2016

Scope of certification

Site Name/location:	Site Addition Date:	Site Address:	Site Scope:
Arion Deutschland GmbH	12-December- 2019	Rutherford 10, 52072 Aachen, Deutschland	Sales and distribution of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients. Sales and distribution of medical devices for donning, doffing and movement aids.

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