

BUREAU VERITAS



Arion Holding B.V.

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

DS/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-2019**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **11-December-2022**

Certificate No.: DNKFRC102102 Version: 2 Revision date: **16-January-2020**

Certification Office: *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**. 1/3

 **DANAK**
SYSTEM Reg.nr. 5005



BUREAU VERITAS



Arion Holding B.V.

Standard

DS/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.

<u>Site Name/location:</u>	<u>Site Addition Date:</u>	<u>Site Address:</u>	<u>Site Scope:</u>
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.

Certificate No.: DNKFRC102102 Version: 2 Revision date: **16-January-2020**

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Arion Holding B.V.

Standard

DS/EN ISO 13485:2016

Scope of certification

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.
Arion Deutschland GmbH	12-December-2019	Rutherford 10, 52072 Aachen, Germany	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.

Certificate No.: DNKFRC102102 Version: 2 Revision date: **16-January-2020**

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