

EU Declaration of Conformity

Regarding the Regulation (EU) 2017/745

Arion Manufacturing B.V.

Rutherford 11
6422 RE Heerlen
Netherlands
Email: manufacturing@arion-group.com
Phone: +31 45 209 4000

SRN: NL-MF-0000020

Hereby declares under its sole responsibility that the product(s) under the product group described below are in accordance with the conformity assessment of MDR risk class I, rule 1 in accordance with annex VIII of regulation (EU) 2017/745 and technical documentation in annex II and III of Regulation (EU) 2017/745.

Basic UDI-DI number
871712793BODY.WASHM6

Product group
Swash Bathing

The following product variants under the Swash Bathing product group are listed in the addendum to this declaration.

Intended purpose: a complete washing and clean-up of incontinent and/or bedridden patients as an infection prevention measure.

Specifically: bathing wipes/gloves for body wash, refreshing wipes for hand/face wash and cleansing (baby) wipes for incontinence clean-up

The Quality Management System of Arion Manufacturing B.V. is certified by Bureau Veritas Certification Denmark A/S according to DS/EN ISO 13485:2016. Certificate Number: DNKFRC102102. Scope of certification of Arion Manufacturing B.V. is design and development, production of medical devices for skin disinfection, cleaning, treatment and protection for bedridden and/or incontinent patients.



The products carry the CE Mark:

This EU Declaration of Conformity is signed for and on behalf of Arion Manufacturing B.V.

Place and date of issue: Heerlen, 14 Nov 2022

C.J.T. Joosten, Chief Operating Officer

O. Hendrawati, Person Responsible for Regulatory Compliance

Addendum: Product Variants of Swash Bathing

The following product variants are part of the product group mentioned in this Declaration of Conformity.

UDI-DI	Product Article Code	Trade name	Items/ pack	Packaging (per box)
08717127936854	A04028-8	Swash Bathing Wipes FF	8	44
08717127937325	A04540-8	Swash Bathing Wipes Spunlace FF	8	56
08717127937134	B04028-8	Swash Bathing Wipes F Orange	8	44
08720663610379	B04540-8	Swash Bathing Wipes Spunlace F Orange	8	56
08717127936847	A04070-8	Swash Bathing Gloves FF	8	40
08717127937196	A04070-6	Swash Bathing Gloves FF	6	52
08717127938070	A04070-5	Swash Bathing Gloves FF	5	60
08717127937189	B04070-8	Swash Bathing Gloves F Orange	8	40
08717127937738	B04070-5	Swash Bathing Gloves F Orange	5	60
08717127937110	A04010-32	Swash Refreshing Wipes FF	32	30
08717127937127	B04010-32	Swash Refreshing Wipes F	32	30
08717127938216	L05012-48	Swash Cleansing Wipes FF	48	12
08717127938223	M05012-48	Swash Cleansing Wipes F	48	12
08720663610485	M05012-24	Swash Cleansing Wipes F	24	24
08720663610454	L05012-72	Swash Cleansing Baby Wipes FF	72	16
08720663610638	P04070-8	Swash Bathing Gloves F Green	8	40
08720663610720	P04540-8	Swash Bathing Wipes Spunlace F Green	8	56
08720663610690	P04028-8	Swash Bathing Wipes F Green	8	44



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autenticada:

the 27th of February 2023

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

- Country: THE NETHERLANDS
This public document
- has been signed by **mr. J.L.G. Fleuren**
- acting in the capacity of notary at Heerlen
- bears the seal/stamp of aforesaid notary

Certified

- in Maastricht
- on 27-02-2023
- by the registrar of the district court of Limburg
- no. 23 / 425

9. Seal/stamp:

10. Signature:



C.M.H.M. Brouwers-Kusters