

EU Declaration of Conformity

Regarding the Regulation (EU) 2017/745

Arion Manufacturing B.V.

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SRN: NL-MF-000002059

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
871712793INCONTINENCENG

Product group
Swash Incontinence

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

Intended purpose: perineal care of incontinent patients as a measure to prevent skin damage associated with exposure to urine or stool (IAD) or as a measure to manage such skin damage (IAD) in an early stage.

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.

Date and place of issue: 03 Feb 2022, Heerlen

C.J.T. Joosten, Chief Operating Officer

O. Hendrawati, Person Responsible for Regulatory Compliance

Addendum: Product Variants of Swash Incontinence

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)
08717127937158	C04533-4	Swash Perineum Wipes	4	64
08717127937165	C04533-8	Swash Perineum Wipes	8	40
08717127937172	C04070-4	Swash Perineum Gloves	4	80
08717127937332	C04070-8	Swash Perineum Gloves	8	40
08717127938186	K04540-8	Swash Perineum Plus Wipes	8	56
08717127938209	K04540-4	Swash Perineum Plus Wipes	4	84



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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
- Seal/stamp:
- Signature:



C.M.H.M. Brouwers-Kusters