

## 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](mailto:manufacturing@arion-group.com)  
 Phone: +31 45 209 4000

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**  
 871712793HAIR.CARECB

**Product group**  
 Swash Haircare

UDI-DI	Product Article Code	Trade name	Items/ pack	Packaging (per box)
08717127937219	D04077-1	Swash Shampoo Cap FF	1	52
08717127937929	G04077-1	Swash Shampoo Cap F	1	52

Intended purpose: intended for a complete hair wash of bedridden patients as an infection prevention measure.

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

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*the 27th of February 2023*  




### APOSTILLE

(Convention de La Haye du 5 octobre 1961)

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

Certified

5. in Maastricht
6. on 27-02-2023
7. by the registrar of the district court of Limburg
8. no. 23 / 425
9. Seal/stamp:
10. Signature:

C.M.H.M. Brouwers-  
Kusters

