

EU Declaration of Conformity

Regarding the Regulation (EU) 2017/745

Arion Slide Solutions B.V.

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hereby declares under its sole responsibility that the products 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

871712793EasySI_MagnideA5

Product group

EasySlide-Magnide

The product variants under the EasySlide-Magnide product group are listed in the Addendum to this declaration.

Intended purpose: Application aids (donning and doffing) for medical compression garments

The Quality Management System of Arion Slide Solutions 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 Slide Solutions B.V. is design and development, production, storage, sales and distribution of medical devices for donning, doffing and movement aids.



The products carry the CE Mark:

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

Place and date of issue: Heerlen, 28 Jan 2025

A handwritten signature in blue ink, appearing to read 'Christine de Kogel'.

Christine de Kogel, R&D Manager / Person Responsible for Regulatory Compliance

Addendum: Product Variants of EasySlide-Magnide

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

UDI-DI	Product Article Code	Trade name	Items/ pack	Packages/ shipper case
8717127930111	E01500	Arion Easy-Slide Extra Small	1	30
8717127930401	E01501	Arion Easy-Slide Small	1	30
8717127930432	E01502	Arion Easy-Slide Medium	1	30
8717127930463	E01503	Arion Easy-Slide Large	1	30
8717127930494	E01504	Arion Easy-Slide Extra Large	1	30
8717127930708	E0SL01	Arion Sim-Slide Small	1	30
8717127930739	E0SL02	Arion Sim-Slide Medium	1	30
8717127930760	E0SL03	Arion Sim-Slide Large	1	30
8717127930791	E0SL04	Arion Sim-Slide Extra Large	1	30
8717127930524	E01513	Arion Magnide Medium	1	30
8717127930555	E01514	Arion Magnide Large	1	30
8717127930586	E01515	Arion Magnide Extra Large	1	30
8717127930616	E01540	Arion Magnide 2in1 Medium	1	30
8717127930647	E01541	Arion Magnide 2in1 Large	1	30
8717127930678	E01542	Arion Magnide 2in1 Extra Large	1	30
8717127930821	E01510	Arion Easy-Off Small	1	30
8717127930852	E01511	Arion Easy-Off Medium	1	30
8717127930883	E01512	Arion Easy-Off Large	1	30
8717127930975	E01520	Arion SlideX Medium	1	30
8717127931002	E01521	Arion SlideX Large	1	30
8717127931040	E01522	Arion SlideX Extra Large	1	30
8717127931385	E01571	Arion Dactyna Small	1	30
8717127931491	E01572	Arion Dactyna Medium	1	30
8717127931521	E01573	Arion Dactyna Large	1	30
8717127930913	E01505	Arion Easy-Slide Arm Medium	1	30
8717127930944	E01506	Arion Easy-Slide Arm Large	1	30
8717127936762	E01700	Arion Easy-Slide Kids Extra Small	1	75
8717127936779	E01701	Arion Easy-Slide Kids Small	1	75
8717127936816	E01712	Arion Magnide Kids Small	1	30
8717127937691	E01770	Arion Dactyna Kids Extra Small	1	50

The following made-to-measure variants are part of the product group mentioned in this Declaration of Conformity:

UDI-DI	Product Article Code	Trade name	Items/ pack	Packages/ shipper case
8717127934409	E0ESM1	Arion Easy-Slide made-to-measure	1	1
8717127934416	E0SSLM1	Arion Magnide made-to-measure	1	1
8717127934423	E0MGM1	Arion Sim-Slide made-to-measure	1	1
8717127934430	E0EOM01	Arion Easy-Off made-to-measure	1	1
8717127934447	E0ESAM1	Arion Easy-Slide Arm made-to-measure	1	1

Version history for internal use (delete it + the yellow marking on the DoC that will be printed)

Version	Effective Date	Reason for Revision
00	23/08/2024	New document for new UDI after packaging change
01		Correction of UDIs for Made To Measure Products.