EU Declaration of Conformity

Regarding the Regulation (EU) 2017/745

Arion Slide Solutions B.V.
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SRN: NL-MF-000002671

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	**Product group**
871712793EasySl_MagnideA5	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

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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: CE

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

Date and place of issue: Heerlen, 22 March 2022

Carl Joosten, CFO / Person Responsible for Regulatory Compliance

Addendum: Product Variants of EasySlide-Magnide

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	Packages/ shipper case
08717127935079	E01500	Arion Easy-Slide Extra Small	1	75
08717127935086	E01501	Arion Easy-Slide Small	1	75
08717127935093	E01502	Arion Easy-Slide Medium	1	75
08717127935109	E01503	Arion Easy-Slide Large	1	75
08717127935116	E01504	Arion Easy-Slide Extra Large	1	50
08717127941261	E0ESM1	Arion Easy-Slide Made-to-measure	1	1
08717127935413	E0SL01	Arion Sim-Slide Small	1	30
08717127935420	E0SL02	Arion Sim-Slide Medium	1	30
08717127935437	E0SL03	Arion Sim-Slide Large	1	30
08717127935444	E0SL04	Arion Sim-Slide Extra Large	1	30
08717127941292	E0SSLM1	Arion Sim-Slide Made-to-measure	1	1
08717127936144	E01513	Arion Magnide Medium	1	30
08717127936151	E01514	Arion Magnide Large	1	30
08717127936472	E01515	Arion Magnide Extra Large	1	30
08717127941278	E0MGM1	Arion Magnide Made-to-measure	1	1
08717127937349	E01540	Arion Magnide 2in1 Medium	1	25
08717127937356	E01541	Arion Magnide 2in1 Large	1	25
08717127937363	E01542	Arion Magnide 2in1 Extra Large	1	25
08717127935178	E01510	Arion Easy-Off Small	1	50
08717127935185	E01511	Arion Easy-Off Medium	1	50
08717127935192	E01512	Arion Easy-Off Large	1	50
08717127941247	E0EOM01	Arion Easy-Off Made-to-measure	1	1
08717127936519	E01520	Arion SlideX Medium	1	20
08717127936625	E01521	Arion SlideX Large	1	20
08717127936823	E01522	Arion SlideX Extra Large	1	20
08717127934058	E01610	Arion Easy-Slide + Easy-Off Small	2	30
08717127934065	E01611	Arion Easy-Slide + Easy-Off Medium	2	30
08717127934072	E01612	Arion Easy-Slide + Easy-Off Large	2	30
08717127934089	E01613	Arion Easy-Slide + Easy-Off Extra Large	2	30
08717127936168	E01619	Arion Magnide + Easy-Off Medium	2	25
08717127936175	E01620	Arion Magnide + Easy-Off Large	2	25
08717127937707	E01571	Arion Dactyna Small	1	30
08717127937714	E01572	Arion Dactyna Medium	1	50
08717127937721	E01573	Arion Dactyna Large	1	50
08717127935123	E01505	Arion Easy-Slide Arm Medium	1	50
08717127935130	E01506	Arion Easy-Slide Arm Large	1	50
08717127941254	E0ESAM1	Arion Easy-Slide Arm Made-to-measure	1	1
08717127936762	E01700	Arion Easy-Slide Kids Extra Small	1	75
08717127936779	E01701	Arion Easy-Slide Kids Small	1	75
08717127936816	E01712	Arion Magnide Kids Small	1	30
08717127937691	E01770	Arion Dactyna Kids Extra Small	1	50