

Declaration of Conformity for Bathing and Washing Aids

Direct Healthcare Group Sverige AB confirm the requirements specified in the Medical Device Regulation 2017/745 have been fulfilled. The EU declaration of conformity is issued under the sole responsibility of DHG Sverige AB. The undersigned has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions, and has carried out operations in accordance with these instructions.

General Product Name	See Appendix II
Legal Manufacturer	Direct Healthcare Group Sverige AB Torshamnsgatan 35 164 40 Kista Sweden
Applicable standards/ Common specifications	As per Appendix I
Intended Use	<p>The Non-Wall Mounted Washing and Bathing Aids are to be used for showering and toileting less active patients with weak legs, a low stamina and/or poor balance who sit on the chair for longer periods of time and who require more support and assistance during bathroom routines under normal use.</p> <p>DHG AB's Bathing and washing aids provide a stable position while showering and washing related activities. The bathing and washing aids come with side fence accessories that protect the user from rolling off the shower trolley. The Bathing and Washing Aids are to be operated by caregivers (lay persons and healthcare professionals).</p> <p>The Swimming Pool Trolley is the only product in this product line with the additional intended use to ride or hoist a patient in and out of a swimming pool.</p>
MDR Classification	Class I, Rule I
Single Registration Number (SRN)	SE-MF-000014152
Registration Agency	Swedish Medical Products Agency
Medical Device Regulation Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name Asal Attabipour **Position** QARA Specialist EU

Signature  **Date and Place** 2022-02-24 Kista

Appendix I – Applicable Standards

Following standards are used to fulfil the Medical Device Regulations and Requirements:

Standards	Description
ISO 17966:2016	Assistive products for personal hygiene that support users — Requirements and test methods
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

Appendix II – Product Listing

Description	Article no	Basic UDI	GMDN
Combi chair, height 455-545, SS/white coated	201903314	7331769013479	34936
Combi chair, height 505-603, SS/white coated	201904314	7331769013455	34936
Combi chair, height 505-603, extra wide, SS/white coated	201911314	7331769031336	34936
Shower Trolley 150 cm white	LI2513.1501-02	7331769026745	34936
Shower Trolley 150 cm SS/white coated	LI2513.1504-02	7331769026769	34936
Shower Trolley 170 cm SS/white coated	LI2513.1701-02	7331769026783	34936
Shower Trolley 170 cm SS/white coated	LI2513.1704-02	7331769026806	34936
Shower Trolley 190 cm white	LI2513.1901-02	7331769026820	34936
Shower Trolley 190 cm SS/white coated	LI2513.1904-02	7331769026844	34936
Shower Trolley 150 cm white	LI2514.1501-02	7331769026868	34936
Shower Trolley 150 cm SS/white coated	LI2514.1504-02	7331769026882	34936
Shower Trolley 170 cm white	LI2514.1701-02	7331769026905	34936
Shower Trolley 170 cm SS/white coated	LI2514.1704-02	7331769026929	34936
Shower Trolley 190 cm white	LI2514.1901-02	7331769026943	34936
Shower Trolley 190 cm SS/white coated	LI2514.1904-02	7331769026967	34936
Swimming Pool Trolley 190 cm SS 316	LI2514.1987-00	7331769026981	34936

Revision log

Version	Date	Amendment
1.0	19/05/2021	First issue for MDR compliance
2.0	25/05/2021	First page typo in the table, Directive changed to Regulation.
3.0	2022-02-24	<ul style="list-style-type: none"> SRN added Document ID changed in accordance with TF Product list was reviewed and products were added /removed (commercial decision) New date format