


Declaration of Conformity for Self-Propelled Shower and Toilet Seating 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 devices are used to assist caregivers in showering routines, cleaning, toileting, changing clothes and moving conscious patients that have reduced or little muscular function safely and comfortably.</p> <p>The devices are mobile to allow transport to and from the bathroom area and transfers and movement within the bathroom area. The devices allow the patient physical support during showering, washing, drying, toileting and dressing in a safe and comfortable sitting position. The armrests will give support for sitting up, and swivel away for easy sideways transfers. All bathroom safety devices have a maximum safe working load as indicated on the labels and in the IFU. All devices can be tailored to the patient's and caregivers needs with the use of accessories.</p> <p>The swimming pool hoist chair may be used as described above and for the use of physical therapy sessions or relaxation in a swimming pool environment.</p> <p>Some variants of the devices, including the combi chair tilt are equipped with keyhole shaped seating surfaces. This allows the user to maneuver the device over a toilet for toileting activities. The devices equipped with a rail underneath the seating surface allow the use of a bedpan for the same purpose.</p>
MDR Classification	Class I, Rule I

SRN	SE-MF-00001452
Registration Agency	Swedish Medical Products Agency
Medical Device Regulation Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name Elisabet Lindberg **Position** Quality and Environmental Specialist

Signature  **Date and Place** 2022-05-10 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	GDMN
chair high soft seat closed white	LI2136.0111-02	07331769023300	34936
chair high soft seat closed SS polished	LI2136.0112-00	07331769023355	34936
chair high soft seat closed SS/white coated	LI2136.0114-02	07331769023362	34936
chair high soft seat open white	LI2136.0211-02	07331769023416	34936
chair high soft seat open SS polished	LI2136.0212-00	07331769023461	34936
chair high soft seat open SS/white coated	LI2136.0214-02	07331769023478	34936
chair low soft seat closed white	LI2136.1111-02	07331769023522	34936
chair low soft seat closed SS polished	LI2136.1112-00	07331769023577	34936
chair low soft seat closed SS/white coated	LI2136.1114-02	07331769023584	34936
chair low soft seat open white	LI2136.1211-02	07331769023638	34936
chair low soft seat open SS polished	LI2136.1212-00	07331769023683	34936
chair low soft seat open SS/white coated	LI2136.1214-02	07331769023690	34936
chair high soft seat closed white	LI2137.0111-02	07331769023744	34936
chair high soft seat closed SS polished	LI2137.0112-00	07331769023799	34936
chair high soft seat closed SS/white coated	LI2137.0114-02	07331769023805	34936
chair high soft seat open white	LI2137.0211-02	07331769023850	34936

chair high soft seat open SS polished	LI2137.0212-00	07331769023904	34936
chair high soft seat open SS/white coated	LI2137.0214-02	07331769023911	34936
chair low soft seat closed white	LI2137.1111-02	07331769023966	34936
chair low soft seat closed SS polished	LI2137.1112-00	07331769024017	34936
chair low soft seat closed SS/white coated	LI2137.1114-02	07331769024024	34936
chair low soft seat open white	LI2137.1211-02	07331769024079	34936
chair low soft seat open SS polished	LI2137.1212-00	07331769024123	34936
chair low soft seat open SS/white coated	LI2137.1214-02	07331769024130	34936
chair Heavy Duty / white	LI2137.5211-02	07331769024185	34936
chair Heavy Duty SS / white coated	LI2137.5214-02	07331769024208	34936
Shower/Commode chair / textile seat high white	LI2140.0001-02	07331769024888	34936
Shower/Commode chair / textile seat high SS polished	LI2140.0002-00	07331769024932	34936
Shower/Commode chair / textile seat high SS/white coated	LI2140.0004-02	07331769024949	34936
Shower/Commode chair / textile seat low white	LI2140.1001-02	07331769024994	34936
Shower/Commode chair / textile seat low SS polished	LI2140.1002-00	07331769025045	34936
Shower/Commode chair / textile seat low SS/white coated	LI2140.1004-02	07331769025052	34936

Revision log

Version	Date	Amendment
1.0	2022-02-24	First issue for MDR compliance
2.0	2022-05-10	Removed article