


## Declaration of Conformity for 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 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.

<b>General Product Name</b>	See Appendix II
<b>Legal Manufacturer</b>	Direct Healthcare Group Sverige AB Torshamnsgatan 35 164 40 Kista Sweden
<b>Applicable standards/ Common specifications</b>	As per Appendix I
<b>Intended Use</b>	<p>The Non-Wall Mounted Shower and Toilet Seating Aids allow the user to sit down safely and comfortably during showering, washing, drying and dressing in safe and comfortable seated position. The armrests will give support getting upright and getting seated and swivel for sideway transfers.</p> <p>With the use of a bedpan or bucket the chair can be used for sanitary needs.</p> <p>The swimming pool chair may be used as described above and for the use of physical therapy sessions or relaxation in a swimming pool environment.</p>
<b>MDR Classification</b>	Class I, Rule I
<b>Registration Agency</b>	Swedish Medical Products Agency
<b>Medical Device Regulation Assessment Route</b>	Annex II of the European Medical Device Regulation (EU) 2017/745

<b>Name</b>	<u>Roshana Eriksson</u>	<b>Position</b>	<u>Head of QARA EU</u>
<b>Signature</b>		<b>Date and Place</b>	<u>25/05/2021 Kista</u>

## 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, manual tilt	201941314	07331769034481	34936
Combi, self-propelled	201921314	07331769031503	34936
Combi, self-propelled, wide	201930314	07331769031510	34936
Self-propelled commode-shower soft seat chair, high & closed seat	LI2138.011	07331769024222	34936
Self-propelled commode-shower soft seat chair, high & open seat	LI2138.021	07331769024338	34936
Self-propelled commode-shower soft seat chair, low & closed seat	LI2138.111	07331769024444	34936
Self-propelled commode-shower soft seat chair, low & open seat	LI2138.121	07331769024550	34936
Self-propelled shower chair, textile seat, high	LI2142.000	07331769025335	34936
Self-propelled shower chair, textile seat, high	LI2142.000	07331769025342	34936
Self-propelled shower chair, textile seat, high	LI2142.000	07331769025380	34936
Self-propelled shower chair, textile seat, high	LI2142.000	07331769025397	34936
Self-propelled shower chair, textile seat, low	LI2142.100	07331769025441	34936
Self-propelled shower chair, textile seat, low	LI2142.100	07331769025496	34936
Self-propelled shower chair, textile seat, low	LI2142.100	07331769025502	34936
Swimming Pool Chair	LI2142.1087-00	07331769031473	34936

**The following articles are accessories to the Shower and Toilet Seating Aids:**

Description	Article no	Basic UDI	GMDN
Amputee Support	201060004	07331769015107	34936
Leg Support	201061004	07331769015114	34936
Armrest Lock	201030310	07331769015039	34936
Footrests	200810004	07331769014971	34936
Headrest	200360004	07331769014988	34936
Hip Belt	200382004	07331769015008	34936
Lateral Trunk Support, right	201070314	07331769015046	34936
Lateral Trunk Support, left	201072314	07331769015138	34936
Seat with Forward Tilt	201120040	07331769015060	34936
Soft Backrest	201130314	07331769014995	34936
Soft Backrest for combi tilt	201131314	07331769015077	34936
Soft Seat, open seat	LI0121.9040-00	07331769022761	34936
Soft Seat, closed seat	LI0121.9050-00	07331769022778	34936
Heel/Calf Strap	200384004	07331769014988	34936
Front Crossbar	201040314	07331769014957	34936
Insert for Soft Toilet Seat	LI09506.306	08713206015359	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.