

## Declaration of Conformity

### Manufacturer

**Company name:** Human Care HC AB  
**Company registration no:** 556494-6332  
**Company address:** Årstaängsvägen 21B 11743 Stockholm, Sweden  
**Eudamed SRN:** SE-MF-000002090

This declaration of conformity is issued under the sole responsibility of Human Care HC AB. Human Care HC AB hereby declare that the Class 1 medical devices specified in the attached product list (Appendix 1) meet the provision of the Medical Device Regulation (EU) MDR 2017/745. This declaration is supported by the Quality System approval to ISO 13485 issued by Lloyd's Register.

All supporting documentation is retained at the premises of the manufacturer.


Details of the products are laid down in the Technical File, which is present at the above-mentioned address. The Technical File complies with the requirements of the Medical Device Regulation (EU) MDR 2017/745.

### Applicable Standards

Harmonized EN standards for 2017/745 (MDR)	Standard title
EN ISO 10535:2021	Hoists for the transfer of disabled persons – Requirements and the test methods
EN 60601-1:2005	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility Requirements and tests
EN ISO 14971:2019	Application of risk management to medical devices
EN ISO 15223-1:2021	Graphical symbols for use in the labelling of medical devices
EN ISO 10993-1:2018	Biological evaluation of medical devices
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices.

Stockholm, 2024-Aug-12

*Signed by authorized signature*



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Stefan Hedelius, CEO

## Product List

### Appendix 1 to Declaration of Conformity

#### Devices

**Category:** Ceiling Lifts

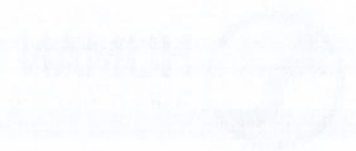
**Intended Purpose:** Patient lifting

**Risk classification:** MDR Class 1 Rule 1

Part number	General device trade name in English	UDI-DI	Basic UDI-DI	GMDN
55100-AU	HeliQ stationary lift 150kg Australia	07331599441091	7331599LB55100H51150HXA	38129
55100-EU	HeliQ stationary lift 150kg Europe	07331599441107		
55100-GB	HeliQ stationary lift 150kg GB	07331599441114		
55100-JP	HeliQ stationary lift 150kg Japan	07331599441121		
55100-NA	HeliQ stationary lift 150kg North America	07331599441138		
55110-EU	HeliQ stationary lift 220kg Europe	07331599441206		
55110-GB	HeliQ stationary lift 220kg GB	07331599441213		
55110-JP	HeliQ stationary lift 220kg Japan	07331599441220		
55110-NA	HeliQ stationary lift 220kg North America	07331599441237		
55110-AU	HeliQ stationary lift 220kg Australia	07331599442098		
55120-AU	HeliQ stationary lift 300kg Australia	07331599441299		
55120-EU	HeliQ stationary lift 300kg Europe	07331599441305		
55120-GB	HeliQ stationary lift 300kg GB	07331599441312		
55120-JP	HeliQ stationary lift 300kg Japan	07331599441329		
55120-NA	HeliQ stationary lift 300kg North America	07331599441336		
55130-AU	HeliQ stationary lift PT (kit) 150kg Australia	07331599441145		
55130-EU	HeliQ stationary lift PT (kit) 150kg Europe	07331599441152		
55130-GB	HeliQ stationary lift PT (kit) 150kg GB	07331599441169		
55130-JP	HeliQ stationary lift PT (kit) 150kg Japan	07331599441176		
55130-NA	HeliQ stationary lift PT (kit) 150kg North America	07331599441183		
55140-AU	HeliQ stationary lift PT (kit) 220kg Australia	07331599441244		
55140-EU	HeliQ stationary lift PT (kit) 220kg Europe	07331599441251		
55140-GB	HeliQ stationary lift PT (kit) 220kg GB	07331599441268		
55140-JP	HeliQ stationary lift PT (kit) 220kg Japan	07331599441275		



55140-NA	HeliQ stationary lift PT (kit) 220kg North America	07331599441282		
55150-AU	HeliQ stationary lift PT (kit) 300kg Australia	07331599441343		
55150-EU	HeliQ stationary lift PT (kit) 300kg Europe	07331599441350		
55150-GB	HeliQ stationary lift PT (kit) 300kg GB	07331599441367		
55150-JP	HeliQ stationary lift PT (kit) 300kg Japan	07331599441374		
55150-NA	HeliQ stationary lift PT (kit) 300kg North America	07331599441381		
Part number	General device trade name in English	UDI-DI	Basic UDI-DI	
55200-AU	Altair 150kg Kit Australia	07331599441398	7331599LA55200H55220HY2	38129
55200-EU	Altair 150kg Kit Europe	07331599441404		
55200-GB	Altair 150kg Kit GB	07331599441411		
55200-JP	Altair 150kg Kit Japan	07331599441428		
55200-NA	Altair 150kg Kit North America	07331599441435		
55200H-EU	Altair 150 kg EU, w/o Hanger Bar	07331599999905		
55200H-GB	Altair 150 kg GB, w/o Hanger Bar	07331599999912		
55200H-JP	Altair 150 kg JP, w/o Hanger Bar	07331599999929		
55200H-AU	Altair 150 kg AU, w/o Hanger Bar	07331599999936		
55200H-NA	Altair 150 kg NA, w/o Hanger Bar	07331599999943		
55210-AU	Altair 220 kg Kit Australia	07331599441442		
55210-EU	Altair 220 kg Kit Europe	07331599441459		
55210-GB	Altair 220 kg Kit GB	07331599441466		
55210-JP	Altair 220 kg Kit Japan	07331599441473		
55210-NA	Altair 220 kg Kit North America	07331599441480		
55210H-EU	Altair 220 kg EU, w/o Hanger Bar	07331599999950		
55210H-GB	Altair 220 kg GB, w/o Hanger Bar	07331599999967		
55210H-JP	Altair 220 kg JP, w/o Hanger Bar	07331599999974		
55210H-AU	Altair 220 kg AU, w/o Hanger Bar	07331599999981		
55210H-NA	Altair 220 kg NA, w/o Hanger Bar	07331599999998		
55220-AU	Altair 300 kg Kit Australia	07331599441497		
55220-EU	Altair 300 kg Kit Europe	07331599441503		
55220-GB	Altair 300 kg Kit GB	07331599441510		
55220-JP	Altair 300 kg Kit Japan	07331599441527		
55220-NA	Altair 300 kg Kit North America	07331599441534		
55220H-EU	Altair 300 kg EU, w/o Hanger Bar	07350011056729		
55220H-GB	Altair 300 kg GB, w/o Hanger Bar	07350011056736		
55220H-JP	Altair 300 kg JP, w/o Hanger Bar	07350011056743		
55220H-AU	Altair 300 kg AU, w/o Hanger Bar	07350011056750		
55220H-NA	Altair 300 kg NA, w/o Hanger Bar	07350011056767		
55300-EU	Roomer S 220kg kit Europe	07331599441046	7331599LC55300H55300H3H	38129
55300-AU	Roomer S 220kg kit Australia	07331599441053		



55300-GB	Roomer S 220kg kit GB	07331599441060		
55300-JP	Roomer S 220kg kit Japan	07331599441077		
55300-NA	Roomer S 220kg kit North America	07331599441084		
55300-AU	Roomer S 220kg - Australia	07331599442173		
55300H-EU	Roomer S 220 kg Europe, w/o Hanger Bar	07350011056774		
55300H-GB	Roomer S 220 kg GB, w/o Hanger Bar	07350011056781		
55300H-JP	Roomer S 220 kg Japan, w/o Hanger Bar	07350011056798		
55300H-AU	Roomer S 220 kg Australia, w/o Hanger Bar	07350011056804		
55300H-NA	Roomer S 220 kg North America, w/o Hanger Bar	07350011056811		
56100-EU	Cosmos lift 150kg/330 lbs EU	07331599724361	7331599LE005610056120KD	38129
56110-EU	Cosmos lift 220kg/484 lbs EU	07331599724378		
56120-EU	Cosmos lift 272kg/600 lbs EU	07331599724385		
56100-NA	Cosmos lift 150kg/330 lbs NA	07331599724392		
56110-NA	Cosmos lift 220kg/484 lbs NA	07331599724480		
56120-NA	Cosmos lift 272kg/600 lbs NA	07331599724415		
56100-GB	Cosmos lift 150kg/330 lbs GB	07331599724422		
56110-GB	Cosmos lift 220kg/484 lbs GB	07331599724439		
56120-GB	Cosmos lift 272kg/600 lbs GB	07331599724446		
56100-JP	Cosmos lift 150kg/330 lbs JP	07331599724453		
56110-JP	Cosmos lift 220kg/484 lbs JP	07331599724460		
56120-JP	Cosmos lift 272kg/600 lbs JP	07331599724477		
56100-AU	Cosmos lift 150kg/330 lbs AU	07331599724484		
56110-AU	Cosmos lift 220kg/484 lbs AU	07331599724491		
56120-AU	Cosmos lift 272kg/600 lbs AU	07331599724507		
<b>Part number</b>	<b>General device trade name in English</b>	<b>UDI-DI</b>	<b>Basic UDI-DI</b>	
70967-EU	FL180 Floor lift Kit Europe	07331599441541	7331599LD007096770967TT	38129
70967-AU	FL180 Floor lift Australia	07331599442180		
70967-EU	FL180 Floor lift Europe	07331599442197		
70967-GB	FL180 Floor lift GB	07331599442203		
70967-JP	FL180 Floor lift Japan	07331599442210		
70967-NA	FL180 Floor lift North America	07331599442227		

See appendix 2 for list of accessories.



Appendix 2

**Accessories**

General trade name in English	Part no.	Basic UDI-DI
Upholstered cover hanger bar	50866	7331599TJ2103456789012SX
Adjustable bumper lifts	20069	7331599TK2100123456789KB
Cover 100	20139	
Adjustable foot SF 35x14xM8x40	20221	
Pole lifts P100 229cm 4P	20226	
Pole lifts P100 235cm 4P	20227	
Support lifts 302cm 2P	20228	
Support lifts 470cm 2P	20230	
Pole lifts P100 265cm 4P	20236	
Pole with leg	20243	
Wall-att. kit	20246	
Travers roller	20385	
Parallel traverse roller 160mm P100	20425	
Travers roller tilt prot P100	20455	
Attachment hook	20496	
Pole for 20802/20803 2-pack	20801	
Pendelum	30125	
Plastic cap - white	40044	
Ceiling attach lift P87-P180	50167	
Plate with screw lift P87-P180	50168	
Washer ceiling attach lift P87-P180	50169	
Travers roller lift P87-P180 pair	50170	
Pendulum adj 100-140mm white	50190	
Pendulum adj 140-180mm white	50191	
Pendulum adj 180-220mm white	50192	
Pendulum adj 220-260mm white	50193	
Pendulum adj 260-300mm white	50194	
End cover P82 with screw	50197	
Wall attach side assembled	50320	
Wall attach side assembled	50321	
Ceil conn without exp.bolt P100	50322	
Trolley lift	50346	
Reacher bar lift 60cm red	50494	
Spacer lift P87-P180 2mm	50495	
Spacer lift P87-P180 5mm	50496	
Connection lift P87-P180 compl	50499	



Adjust pendelum 520-1400mm unpainted	50760-1400	7331599TK2100123456789KB
Adjust pendelum 260-360mm unpainted	50760-360	
Adjust pendelum 340-520mm unpainted	50760-520	
Wood ceiling attach P87-P180	53008	
Self tapp screw 5,5x50 w P87-P180	53014	
Traverse roller raised P87-P180	53022	
Rail nut lift P87-P180	53024	
Wall attach bracket lifts P87-P180	53025	
Poles 2700mm, 2 pack	53027	
Pole complete P87-P180 2P	53030	
Shackle D 3/8"	53043	
Plate with Screw 50mm 10pcs	53049	
Contactor for power rails	54110	
Contactor IRC power cable	54111	
IRC entry guide	54115	
IRC unit cpl	54301	
Traverse roller IRC	54308	
Cable (5, Medium) IRC-connector-charger	54321	
Electrical rail -Trolley	54336	
IRC kit for Power Traverse	54907	
Support for traverse trolley	55654	
Base piece interlocking unit	55657	
Left Cover Interlock	55730	
Charging station IRC rail rollers	71326	
Traverse carriage Low P87-180 pair	71837	
Charging station Power traverse cpl	71838	
Pole leg complete 2 pack	71839	
Hanger bar portable lift 4P	55619	7331599TO21045678901233L
Hanger bar, FL180 mobile lift (x cm)	70977 , 70978 , 70979	
Hanger bar Altair/Roomer-S 2P 35 cm	55763	
Hanger bar Altair/Roomer-S 2P 45 cm	55751	
Hanger bar Altair/Roomer-S 2P 55 cm	55764	
Hanger bar HeliQ lift 2P 45cm	54043, 72755	
Hanger bar HeliQ lift 2P 35cm	72754	
Hanger bar HeliQ lift 2P 60 cm	72757	
Hanger bar HeliQ lift 4P	92938	
Gate	55721	
4-point spreader bar oh lift, Small	92441	7331599TR21078901234566W
Powered 4-point spreader bar, Medium	92442	
Powered 4P spreader bar, Large	92443	
Distance strap lifts (x CM) 2 hooks	See to the left	7331599TM2102345678901UH

[part no: 20124-10, 20124-15, 20124-20, 20124-25, 20124-30, 20124-35, 20124-40, 20124-45, 20124-50, 20124-55, 20124-60, 20124-65, 20124-70, 20124-75, 20124-80, 20124-85, 20124-90, 20124-95, 20124-100, 20124-110, 20124-120, 20124-140]		
Distance strap lift (x CM) catch hook [part no: 20124S-15, 20124S-20, 20124S-30, 20124S-50, 20124S-80, 20124S-210]	See to the left	
Turntable	91884	7331599TQ21067890123456U
Bag Niklas Freestand lift red	50599	7331599TN2103456789012YB
Niklas portable freestand	50600	
Lena freestand lifts 2,5m	71806	
Pole complete 2 pack	71807	
Lena freestand lifts 3m	71808	
Putti freestand for Japan, 2,5, Medium	71841	
Rail roller with loop lifts	20107	
Travers roller lifts P100	20133	7331599TL2101234567890Q3
Rail roller with hook lifts	20529	
Travers roller elevat 70mm P100	20540	
Rail P110 3950mm	50183	
Curve 80 - 45°	50256	
Curve 80 - 30°	50257	
Curve P82 45° L=500mm	50476	
Curve P82 60° L=500mm	50477	
Curve P82 90° L=500mm	50478	
Curve P82 90° L=1000mm	50479	
Shelf profile P82	50490	
Rail roller 39mm	53031	
Rail roller stationary, curtain gap	54300	
Rail roller stationary,curtain,IRC	54302	
IRC power rail, 1, Medium	54324	
P87 curve rails 45 degree 500mm	55601	
P87 curve rails 60 degree 500, Medium	55602	
P87 curve rails 90 degree 500mm	55603	
P87 curve rails 90 degree 1000mm	55604	
Endcap Rail P87	55605	
Endcap Rail P120	55606	7331599TL2101234567890Q3
Endcap P87 rails with screws	55608	
Endcap P120 rails with screws	55609	
Endcap P180 rails with screws	55610	
Rail roller HeliQ lift	55618	
Pin 4,5x25	71217	
P87 rail 2500mm	71236	
P87 rail 2500mm, Medium rail profile	71236H	
P87 rail 3000mm	71237	



P87 Rail 3000, Medium w rail profile	71237H
P87 rail 4000mm	71238
P87 Rail 4000, Medium w rail profile	71238H
P87 rail 5500mm	71239
P87 rail 7000mm	71240
P87 Rail 5500, Medium with profile	71240H
P120 rail 3000mm	71241
P120 rail 4000mm	71242
P120 rail 5000mm	71243
P120 rail 6200mm	71244
P180 rail 5500mm	71245
P180 rail 7000mm	71246
Rail roller stationary IRC	71353
Rail roller portable w loop 31mm	71381
Rail roller portable hook 31mm	71382
Rail roller stationary 31mm	71383
Rail roller portable w loop 37mm	71384
Rail roller portable hook 37mm	71385
Rail roller stationary 37mm	71386
Rail roller portable w loop 39mm	71387
Rail roller portable hook 39mm	71388
Rail roller stationary 39mm	71389
Rail roller portable w loop 41mm	71390
Rail roller portable hook 41mm	71391
Rail roller stationary 41mm	71393
Rail roller stationary w IRC 31mm	71394
Rail roller stationary w IRC 37mm	71395
Rail roller stationary w IRC 39mm	71396
Rail roller stationary w IRC 41mm	71397
Rail Roller stationary lifts, High	90551

## History

Version	Valid from (replaces the previous version from):	Note:
1.0	2021-05-17	First MDR-DoC release
2.0	See approval signature date	This document
3.0	2022-01-19	Added GMDN codes to UK registered products in appendix 1.
4.0	2022-02-03	Added GMDN codes to Heliq and FL180
5.0	2023-01-26	Standards revised, Rule info and rev info were added.
6.0	2024-06-03	Added Cosmos