

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 the manufacturer.

Human Care HC AB hereby declares that medical devices specified in the attached product list in Appendix 1 comply with the provision of the Regulation (EU) 2017/745 on medical devices.

The devices are classified as Class I in accordance with Annex VIII, Rule 1 of Regulation (EU) 2017/745.

The conformity assessment procedure has been carried out in accordance with Article 52(7) and Annexes II and III of Regulation (EU) 2017/745.

The devices comply with the General Safety and Performance Requirements (GSPR) set out in Annex I of Regulation (EU) 2017/745.

The manufacturer operates a Quality Management System in accordance with EN ISO 13485:2016. The Quality Management System is certified by LRQA.

Applicable Standards

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.
EN 1985:1999	Walking aids. General requirements and test methods
ISO 11199-2:2021	Walking aids manipulated by both arms - Requirements and test methods – Part 2: Rollators
ISO 11199-3:2005	Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables

Stockholm, 2026-03-16

Sign by authorized signature



Mikael Jomer, CEO

Product List

Appendix 1 to Declaration of Conformity

Devices

Category: Walking Aids

Intended Purpose: Walking support

Risk classification: Class I according to Annex VIII, Rule 1 of Regulation (EU) 2017/745.

Part number	General device trade name in English	UDI-DI	Basic UDI-DI	GMDN
11150Q1	Carl-Oskar 57 Single pack	07331599111505	7331599RA001115061425HS	37951
11150Q6	Carl-Oskar 57 Six pack	07331599645604		
11150-HB	Carl-Oskar 57 Single-hand brake R	07331599645642		
11150-VB	Carl-Oskar 57 Single-hand brake L	07331599645659		
11150Q1B	Carl-Oskar 57 with basket Single pack	07331599645680		
11150Q6B	Carl-Oskar 57 with basket Six pack	07331599645697		
11151Q1	Carl-Oskar 57 Air wheel	07331599111512		
11151Q6	Carl-Oskar 57 Air wheel (6 pack)	07331599645703		
11154	Carl-Oskar 57 High	07350011058969		
11250Q1	Carl-Oskar 62 Single pack	07331599112502		
11250Q6	Carl-Oskar 62 Sex pack	07331599645611		
11250-HB	Carl-Oskar 62 Single-hand brake R	07331599645666		
11250-VB	Carl-Oskar 62 Single-hand brake L	07331599645673		
11250Q1B	Carl-Oskar 62 with basket Single pack	07331599645727		
11250Q6B	Carl-Oskar 62 with basket Six pack	07331599645734		
11251Q1	Carl-Oskar 62 Air wheel Single pack	07331599112519		
11251Q6	Carl-Oskar 62 Air wheel Six pack	07331599645741		
11254	Carl-Oskar 62 High	07350011058709		
11350Q1	Carl-Oskar 67 Single pack	07331599113509		
11350Q6	Carl-Oskar 67 Six pack	07331599645628		
11350Q1B	Carl-Oskar 67 with basket Single pack	07331599645758		
11350Q6B	Carl-Oskar 67 with basket Six pack	07331599645765		
11350-HB	Carl-Oskar 67 Single-hand brake R	07331599645888		
11350-VB	Carl-Oskar 67 Single-hand brake L	07331599645895		
11351Q1	Carl-Oskar 67 Air wheel Single pack	07331599113516		
11351Q6	Carl-Oskar 67 Air wheel Six pack	07331599646069		
11354	Carl-Oskar 67 High	07350011058983		
11450Q1	Carl-Oskar 72 Single pack	07331599114506		
11450Q6	Car-Oskar 72 Six pack	07331599645772		
11450Q6B	Car-Oskar 72 with basket Single pack	07331599645789		
11450Q1B	Car-Oskar 72 with basket Six pack	07331599645796		
11450-HB	Carl-Oskar 72 Single-hand brake R	07331599645901		

Part number	General device trade name in English	UDI-DI		
11450-VB	Carl-Oskar 72 Single-hand brake L	07331599646076		
11451Q1	Carl-Oskar 72 Air wheel Single pack	07331599114513		
11451Q6	Carl-Oskar 72 Air wheel Six pack	07331599646083		
11454	Carl-Oskar 72 High	07350011058990		
61225	Carl-Oskar 62 Reinforced	07331599612255		
61225B	Carl-Oskar 62 Reinforced with basket	07331599645598		
61325-HB	Carl-Oskar 67 Reinforced Single-hand brake R	07331599993880		
61325-VB	Carl-Oskar 67 Reinforced Single-hand brake L	07331599993897		
61325	Carl-Oskar Roll 67 - 275kg	07331599613252		
61425	Carl-Oskar 72 Reinforced	07331599614259		
12315	Carl-Oskar RA 67 Low	07331599123157	7331599RG001231513425RZ	37951 63867
12315-1	Carl-Oskar RA 67 Low with seat	07331599644829		
12325	Carl-Oskar RA 67	07331599123256		
12325-1	Carl-Oskar RA 67 with seat	07331599644843		
12415	Carl-Oskar RA 72 Low	07331599124154		
12415-1	Carl-Oskar RA 72 Low with seat	07331599644867		
12425	Carl-Oskar RA 72	07331599124253		
12425-1	Carl-Oskar RA 72 with seat	07331599644874		
13315	Carl-Oskar TW 67 Low	07331599133156		
13325	Carl-Oskar TW 67	07331599133255		
13415	Carl-Oskar TW 72 Low	07331599134153		
13425	Carl-Oskar TW 72	07331599134252		
22140Q1	Rebel 57 one pack	07331599221402	7331599RB002214071421L9	37951
22140Q6	Rebel 57 six pack	07331599645635		
22141	Rebel 57 Low	07331599221419		
22144	Rebel 57 High	07350011059003		
22240Q1	Rebel 62 one pack	07331599222409		
22240Q6	Rebel 62 six pack	07331599645826		
22241	Rebel 62 Low	07331599222416		
22244	Rebel 62 High	07350011059010		
22340Q1	Rebel 67 one pack	07331599223406		
22340Q6	Rebel 67 six pack	07331599645864		
22341	Rebel 67 Low	07331599223413		
22344	Rebel 67 High	07350011059027		
22440Q1	Rebel 72 one pack	07331599224403		
22440Q6	Rebel 72 six pack	07331599645871		
22441	Rebel 72 Low	07331599224410		
22444	Rebel 72 High	07350011059034		
71221	Rebel 62 Reinforced	07331599712214		
71321	Rebel 67 Reinforced	07331599713211		
71421	Rebel 72 Reinforced	07331599714218		

22311	Rebel RA 67 Low	07331599223116	7331599RH002231123421SN	37951
22311-1	Rebel RA 67 Low with seat	07331599223550		
Part number	General device trade name in English	UDI-DI		
22321	Rebel RA 67	07331599223215		
22321-1	Rebel RA 67 with seat	07331599644898		
22411	Rebel RA 72 Low	07331599224113		
22411-1	Rebel RA 72 Low with seat	07331599644904		
22421	Rebel RA 72	07331599224212		
22421-1	Rebel RA 72 with seat	07331599644911		
23311	Rebel TW 67 Low	07331599233115		
23321	Rebel TW 67	07331599233214		
23411	Rebel TW 72 Low	07331599234112		
23421	Rebel TW 72	07331599234211		
42221	Staffan RA Low	07331599422212	7331599RI004222143221W3	37951
42231Q1	Staffan RA High one pack	07331599422311		
43211Q1	Staffan TW Low one pack	07331599432112		
43221	Staffan TW High	07331599432211		
470018	neXus 3 Super Low	07350011056927	7331599RF4700184900225A	37951
470022	neXus 3 Low	07350011056910		
470024	neXus 3 Standard	07350011056903		
473118	neXus 3 Super Low FRONTIER Tall	07350011059058		
473022	neXus 3 Low FRONTIER	07350011059065		
473024	neXus 3 Standard FRONTIER	07350011059072		
475018	neXus 3 Super Low RUSSKA	07350011057733		
475018B	neXus 3 Super Low RUSSKA Blue	07350011059188		
475018R	neXus 3 Super Low RUSSKA Red	07350011059218		
475022	neXus 3 Low RUSSKA	07350011057726		
475022B	neXus 3 Low RUSSKA Blue	07350011059171		
475022R	neXus 3 Low RUSSKA Red	07350011059201		
475024	neXus 3 Standard RUSSKA	07350011057719		
475024B	neXus 3 Standard RUSSKA Blue	07350011059164		
475024R	neXus 3 Standard RUSSKA Red	07350011059195		
490017	neXus oNe Super Low	07350011059089		
490020	neXus oNe Low	07350011059096		
490022	neXus oNe Standard	07350011059102		
479022	nexus 3 wide Low	07331599727003		
479024	nexus 3 wide Standard	07331599726990		
53211	Svea TW 59 Low	07331599532119	7331599RJ005321153421Z4	63867
53221	Svea TW 59	07331599532218		
53411	Svea TW 68 Low	07331599534113		
53421	Svea TW 68	07331599534212		
85400Q1	Fellow Supreme one pack	07331599854006	7331599RC008540085400VR	37951
85400Q6	Fellow Supreme six pack	07331599644652		
85500Q1	Parade one pack	07331599855003	7331599RE008550085500Z3	
88009Q1	Fellow Classic Std one pack	07331599880098	7331599RD00880098860944	

88009Q8	Fellow Classic Std eight pack	07331599644553		
88109Q1	Fellow Classic Low One pack	07331599881095		
88309Q1	Fellow Classic Wide one pack	07331599883099		
88509Q1	Fellow Classic Narrow one pack	07331599885093		
88609Q1	Fellow Classic High one pack	07331599886090		

See appendix 2 for list of accessories.

Appendix 2

Accessories

Part number	General device trade name in English	UDI-DI	Basic UDI-DI	GMDN
22115	HP handle. left C-O & Rebel	07331599221150	7331599TA11001234567894L	17105
22116	HP handle right C-O & Rebel	07331599221167	7331599TA11001234567894L	17105
4510	Hard basket Nexus	07350011057696	7331599TB11012345678909C	38495
80702	Tray Nexus	07331599440964	7331599TB11012345678909C	16221
80703	Cane holder complete Nexus	07331599440247	7331599TB11012345678909C	46936
90394	Cup holder	07331599003558	7331599TB11012345678909C	30099
55799	Cross handle Fellow	07350011056880	7331599TA11001234567894L	17105
10621	Back strap, C-O, Rebel,57,62,67	07331599106211	7331599TB11012345678909C	13356
10655	Back strap 72 (bred)	07331599106556	7331599TB11012345678909C	13356
10668	Back strap Fellow	07331599106686	7331599TB11012345678909C	13356
10603	Cane holder	07331599106037	7331599TB11012345678909C	46936
10605	Basket to Carl-Oskar,Rebel- squary	07331599003565	7331599TB11012345678909C	38495
10651	Tray C-O, Rebel	07331599106518	7331599TB11012345678909C	16221
10615	Oxygen tank holder 1,5 - 5 L	07331599106150	7331599TA11001234567894L	41756
91095	Bag kit Rebel and C-O 57, 62	07331599003572	7331599TB11012345678909C	38495
92907	IV-pole for Rebel and Carl-Oskar	07350011057320	7331599TA11001234567894L	36069
91096	Bag kit Rebel and C-O 67, 72	07331599003589	7331599TB11012345678909C	38495
08805	Basket, Fellow Standard	07331599088050	7331599TB11012345678909C	38495
88051	Basket, Fellow Low	07331599106853	7331599TB11012345678909C	38495
88052	Basket, Fellow Narrow, Wide, High	07331599106860	7331599TB11012345678909C	38495
08814	Intravenous stand, Fellow Classic	07331599088142	7331599TA11001234567894L	36069
08811	Oxygen holder, Fellow	07331599088111	7331599TA11001234567894L	41756
08808	Bag, Fellow Standard, Narrow, Wide	07331599088081	7331599TB11012345678909C	38495
08806	Tray, Fellow	07331599088067	7331599TB11012345678909C	16221
10671	Oxygen tank holder, Fellow Supreme	07331599106716	7331599TA11001234567894L	41756
10667	Tray, Fellow Supreme	07331599106679	7331599TB11012345678909C	16221
10666	Basket, Fellow Supreme	07331599106662	7331599TB11012345678909C	38495
10675	Cane holder Parade	07331599106754	7331599TB11012345678909C	46936
10664	Tray for Parade 60	07331599106648	7331599TB11012345678909C	16221
10662	Basket Parade	07331599106624	7331599TB11012345678909C	38495
40603	Cane holder, Staffan	07331599406038	7331599TB11012345678909C	46936
40601	Basket,Staffan RA and Walking Table	0733159940601	7331599TB11012345678909C	38495

History

Version	Valid from (replaces the previous version from):	Note:
1.0	2021-05-20	First MDR-DoC release
2.0	2021-10-08	UDI-DI added to DoC
3.0	See approval signature date	UDI-DI updated to 14 digits
4.0	2022-08-16	Added Nexus in Blue and Red. Added accessories plus Basic UDI-DI's for the additions. Added GMDN codes.
5.0	2023-01-26	Standards revised, Rule info and rev info were added.
6.0	2026-03-16	nexus 3 wide Low and Standard were added.