

Declaration of Conformity

Manufacturer

Company name: Human Care HC AB

Company registration no: 556494-6332

Company address: Årstaängsvägen 21B 11760 Stockholm, Sweden

Eudamed SRN: SE-MF-000002090

This EU 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

EN ISO 10535:2021	Hoists for the transfer of disabled persons – Requirements and the test methods
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
EN ISO 3758:2023	Textiles – Care labelling code using symbols
IEC 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices.

Stockholm, 2025-May-09

Signed by authorized signature



Mikael Jomer, CEO

Product List

Appendix 1 to Declaration of Conformity

Devices

Category: Slings

Intended Purpose: Patient lifting

Risk classification: MDR Class 1 Rule 1

Part number	UDI-DI	General device trade name in English	Basic UDI-DI	GMDN
25005C-JM 25005C-S 25005C-M 25005C-L 25005C-XL 25005C-XXL 25005C-XXXL	07350011058273 07350011058280 07350011058297 07350011058303 07350011058310 07350011058327 07331599002902	Full Body Sling E-clip Net	7331599SB25005C25140C4E	37480
25006C-JS 25006C-JM 25006C-S 25006C-M 25006C-L 25006C-XL 25006C-XXL 25006C-XXXL	07350011059836 07350011059843 07350011059850 07350011059867 07350011059874 07350011059881 07350011059898 07350011059904	Full Body Sling In-Situ E-clip Net		
25010C-JS 25010C-JM 25010C-S 25010C-M 25010C-L 25010C-XL 25010C-XXL 25010C-XXXL	07350011059270 07350011058334 07350011058341 07350011058358 07350011058365 07350011058372 07350011058389 07331599002919	Full Body Sling E-clip Soft		
25011C-JS 25011C-JM 25011C-S 25011C-M 25011C-L 25011C-XL 25011C-XXL 25011C-XXXL	07350011059287 07350011059294 07350011059300 07350011059294 07350011059317 07350011059324 07350011059331 07350011059928	Full Body Sling In-Situ E-clip Soft		
25040C-JS 25040C-JM 25040C-S 25040C-M 25040C-L 25040C-XL 25040C-XXL	07350011059355 07350011059348 07350011058396 07350011058402 07350011058419 07350011058426 07350011059690	Columbus Sling E-clip Soft		
25085C-JM 25085C-S 25085C-M 25085C-L 25085C-XL	07331599002940 07331599002933 07331599002957 07331599002964 07331599002971	Toileting Sling E-clip Net		

Part number	UDI-DI	General device trade name in English	Basic UDI-DI	GMDN
25090C-JM 25090C-S 25090C-M 25090C-L 25090C-XL 25090C-XXL	07331599002889 07331599002872 07350011058433 07350011058440 07350011058457 07350011058464	Toileting Sling High E-clip Net	7331599SD002513025130QH	37480
25091C-JS 25091C-JM 25091C-S 25091C-M 25091C-L 25091C-XL	07331599724293 07331599724187 07331599724194 07331599724170 07331599724200 07331599724217	Toileting Sling High E-clip Soft		
NSB-103C-S NSB-103C-M NSB-103C-L NSB-103C-XL	07331599441718 07331599441725 07331599441732 07331599441749	General Purpose Sling w clips		
25130C-S 25130C-M 25130C-L 25130C-XL	07350011058471 07350011058488 07350011058495 07350011058501	Back Belt E-clip		
NSB-105-S NSB-105-M NSB-105-L NSB-105-XL NSB-109-2XPH	07331599001650 07331599001660 07331599001677 07331599001684 07331599001646	General Purpose Sling Single Patient Use		
NSB-451-U NSB-451-A NSB-451-S	07331599001639 07331599440094 07331599003022	Positioning Sling		
NSB-451-DT	07331599003534	Positioning Sling Soft - Single Patient Use		
25100-JS 25100-JM 25100-JL 25100-S	07350011055098 07350011055104 07350011055111 07350011057085	Activity Sling		
25105-S 25105-M 25105-L 25105-XL	07350011055128 07350011055135 07350011055142 07350011055159	Multi Sling	7331599SC002510025130MM	37480
25130-S 25130-M 25130-L 25130-XL	07331599440971 07331599440988 07331599440995 07331599441008	Back Belt		
25005-S 25005-M 25005-L 25005-XL	07350011050055 07350011050062 07350011050079 07350011050086	Full Body Sling Net		
25010-S 25010-M 25010-L 25010-XL	07350011050109 07350011050116 07350011050123 07350011050130	Full Body Sling	7331599SA002500525140LL	37480

25010-XXL 25010-XXXL	07331599645345 07331599645352		
25015-JS 25015-JM 25015-S 25015-M 25015-L 25015-XL	07350011051151 07350011051168 07350011051175 07350011051182 07350011051199 07350011052110	Silhouette Sling Net	
25018-JS 25018-JM 25018-S 25018-M 25018-L 25018-XL	07331599003480 07331599003497 07331599003473 07331599003428 07331599003503 07331599003510	Silhouette Sling Net padded leg	
25019-JS 25019-JM 25019-S 25019-M 25019-L 25019-XL	07331599003251 07331599003268 07331599003275 07331599003282 07331599003299 07331599003305	Silhouette Sling Soft	
25020-JS 25020-JM 25020-S 25020-M 25020-L 25020-XL	07350011050208 07350011050215 07350011050222 07350011050239 07350011050246 07350011050253	Silhouette Sling Trevira	
25030-JS 25030-JM 25030-S 25030-M 25030-L 25030-XL	07350011050307 07350011050314 07350011050321 07350011050338 07350011050345 07350011051304	Sit Sling	
25032-JS 25032-JM 25032-S 25032-M 25032-L 25032-XL 25032-XXL	07331599002568 07331599002551 07331599002599 07331599002582 07331599002575 07331599002605 07331599440667	High Basic Sling	
25035-JS 25035-JM 25035-S 25035-M 25035-L 25035-XL	07331599252031 07350011056552 07350011050352 07350011050369 07350011050376 07350011050383	Bath Sling	
25037-JS 25037-JM 25037-S 25037-M 25037-L 25037-XL 25037-XXL	07331599002681 07331599002674 07331599002711 07331599002704 07331599002698 07331599002728 07331599440674	High Basic Sling Net	

25040-JM 25040-S 25040-M 25040-L 25040-XL	07350011056576 07350011050406 07350011050413 07350011050420 07350011050437	Amputee Sling
25045-JS 25045-JM 25045-S 25045-M 25045-L 25045-XL 25045-XXL	07350011050451 07350011050468 07350011050475 07350011050482 07350011050499 07350011050505 07331599440681	Basic Sling Net
25047-JM 25047-JS 25047-S 25047-M 25047-L 25047-XL 25047-XXL	07331599002612 07331599002629 07331599002650 07331599002643 07331599002636 07331599002667 07350011059706	Low Basic Sling Net
25050-JS 25050-JM 25050-S 25050-M 25050-L 25050-XL	07350011050529 07350011050512 07350011050536 07350011050543 07350011050550 07350011050567	Basic Sling Trevira
25054-JS 25054-JM 25054-S 25054-M 25054-L 25054-XL	07331599003190 07331599003206 07331599003213 07331599003220 07331599003237 07331599003244	Basic Sling Soft
25060-JM 25060-S 25060-M 25060-L 25060-XL	07350011050611 07350011050628 07350011050635 07350011050642 07350011050659	Comfort Sling Trevira
25064-JM 25064-S 25064-M 25064-L 25064-XL	07331599003084 07331599003091 07331599003107 07331599003114 07331599003121	Comfort Sling Soft
25074-JM 25074-S 25074-M 25074-L 25074-XL	07331599726129 07331599726143 07331599726150 07331599726136 07331599726167	Comfort Sling Net
25065-S 25065-M 25065-L 25065-XL	07350011050666 07350011050673 07350011050680 07350011050697	Comfort Sling High Trevira
25069-JM 25069-S 25069-M 25069-L 25069-XL	07331599003145 07331599003152 07331599003169 07331599003176 07331599003183	Comfort Sling High Soft

7331599SA0025074JMC6

25079-JM 25079-S 25079-M 25079-L 25079-XL	07331599726174 07331599726181 07331599726198 07331599726204 07331599726211	Comfort Sling High Net		
25070-JS 25070-JM 25070-S 25070-M 25070-L 25070-XL 25070-XXL	07331599440063 07331599440070 07331599440087 07331599440094 07331599440100 07331599440117 07331599440698	Basic Sling		
25072-JS 25072-JM 25072-S 25072-M 25072-L 25072-XL 25072-XXL	07331599002506 07331599002490 07331599002537 07331599002520 07331599002513 07331599002544 07350011059713	Low Basic Sling		
25080-JS 25080-JM 25080-S 25080-M 25080-L 25080-XL	07350011050802 07350011050819 07350011050826 07350011050833 07350011050840 07350011050857	Toileting Sling		
25085-JM 25085-S 25085-M 25085-L 25085-XL	07331599252574 07350011055180 07350011055173 07350011055166 07350011055197	Toileting Sling Net		
25090-JM 25090-S 25090-M 25090-L 25090-XL	07350011055302 07350011055050 07350011055067 07350011055074 07350011055081	Toileting Sling High Net		
25120-S 25120-M 25120-L 25120-XL	07331590440124 07331590440131 07331590440148 07331590440155	Highback Plusline Sling		
25140-JM 25140-S 25140-M 25140-L 25140-XL	07350011056941 07350011056972 07350011056965 07350011056958 07350011056989	Amputee Sling Net		
25080B-JS 25080B-JM 25080B-S 25080B-M 25080B-L 25080B-XL	07331599724712 07331599724729 07331599724736 07331599724743 07331599724750 07331599724767	Toileting sling w. Belt	7331599 SA25080B25090B5V	
25090B-JM 25090B-S 25090B-M 25090B-L 25090B-X	07331599724774 07331599724781 07331599724798 07331599724804 07331599724811	Toileting Sling High Net w belt		
NSB-401-S	07331599442074	Positioning Sling standard w loops	7331599SGNSB401NSB41044	38869

NSB-401-ST	07331599995198	Positioning Sling ventilated material, Medium		
NSB-410-ST-L	07331599996249	Bariatric Positioning Sling		
NSB-410-ST-XL	07331599996256	ventilated material		
NSB-104C-S	07331599995501	General Purpose Sling SPU	7331599SENSB104NSB104YK	37480
NSB-104C-M	07331599995518	w clips		
NSB-104C-L	07331599995525			
NSB-104C-XL	07331599995532			
NSB-501C-S	07331599995440	Back Belt Single Patient	7331599SINSB501NSB5017H	37480
NSB-501C-M	07331599995457	Use Clips		
NSB-501C-L	07331599995464			
NSB-501C-XL	07331599996263			
NSB-501-S	07331599995471	Back Belt, Single Patient	7331599SJNSB501NSB5018S	37480
NSB-501-M	07331599995488	Use		
NSB-501-L	07331599995495			
25700-M	07350011058518	Limb Sling	7331599SK25700MNSB010FH	37480
NSB-010	07350011057092			

See appendix 2 for list of accessories.

Appendix 2

Accessories

Part number	UDI-DI	General device trade name in English	Basic UDI-DI
21146-S 21146-M 21146-L	07331599645369 07350011056590 07331599645383	Leg protection slings fur	7331599TG2100123456789DX
21181	07331599211816	Leg padding for Multi Sling	
25102	07331599251027	Reinforced leg supports for slings	
21180-10 21180-15 21180-20 21180-25 21180-35	07350011055319 07350011055326 07350011055333 07350011055340 07331599253106	Extension loop slings (x CM)	7331599TH2101234567890JP
25107-S 25107-M 25107-L	07350011052103 07350011055272 07350011052899	Hip belt Multi Sling	7331599TI2102345678901P5
25145-60 25145-70 25145-80 25145-90 25145-100 25145-110 25145-120 25145-130 25145-140	07350011056347 07350011051441 07350011051458 07350011051465 07350011051472 07350011051489 07350011051502 07331599253014 07331599253021	Waist belt slings velcro (x CM)	
25145-40B 25145-50B 25145-60B	07350011051410 07350011051427 07350011056354	Waist belt slings velcro (x CM) child	
25146-60 25146-70 25146-80 25146-90 25146-100 25146-110 25146-120 25146-130	07350011056392 07350011056170 07350011056187 07350011056194 07350011056200 07350011056217 07350011056408 07331599253076	Waist belt slings buckle (x CM)	
25146-40B 25146-50B 25146-60B	07350011056361 07350011056378 07350011056385	Waist belt slings buckle (x CM) child	
25108	07350011055227	Leg Support, Multi Sling	7331599TJ2103456789012SX
25109	07350011055234	Shoulder Support, Multi Sling	
25150	07350011056224	Neck pillow slings	

History

Version	Valid from (replaces the previous version from):	Note:
1.0	2021-05-18	First MDR-DoC release
2.0	2021-09-20	UDI-DI added to DoC
3.0	See approval signature date	UDI-DI updated to 14 digits
4.0	2022-04-25	Added new sling 25018-*SIZE*
5.0	2022-09-23	Added 25032-XXL, 25037-XXL, 25045-XXL, 25070-XXL, 25010C-JS, 25011C-JS-JM-S-M-L-XL-XXL
6.0	2023-01-23	Standards revised, Rule info and rev info were added.
7.0	2023-07-31	Added 25006-JS-JM-S-M-L-XL-XXL-XXXL, 25011C-XXXL, 25040C-JS, 25040C-JM, 25040C-XL, 25040C-XXL, 25047-XXL, 25072-XXL.
8.0	2024-06-03	Added 25091C-JS-JM-S-M-L-XL
9.0	2024-08-16	GMDN codes added for the Slings.
10	2024-08-22	Added 25080B- JS-JM-S-M-L-XL, 25090B- JS-JM-S-M-L-XL, NSB-451-DT
11	2025-05-08	Added Comfort sling Net 25074-X, and Comfort Sling Net high 25079-X.