

Declaration of Conformity for Walkers

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	Walkers are indoor, movable and portable assistive aids, which together with approved accessories are intended to be used for transfer from sitting to standing positions, and walking training. Walkers are to be used by persons with reduced muscular strength, who shall be able to stand and perform simple leg movements. Walkers are to be used for leaning on when walking and standing during early mobilization training. Walkers and accessories are intended to be used in Home Healthcare environment and Professional Healthcare facility environment.
MDR Classification	Class I, Rule I and Rule XIII
Single Registration no (SRN):	SE-MF-000014152
Registration Agency	Swedish Medical Products Agency
Assessment Route	Annex II of the European Medical Device Regulation (EU) 2017/745

Name Elisabet Lindberg **Position** Head of Quality and Environmental Europe

Signature  **Date and Place** 2024-10-09, Kista

Appendix I – Applicable Standards

Following standards are used to fulfil the Medical Device Regulations and Requirements:

Standard	Description
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
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
IEC 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests As applicable to the electrically powered Articles.
IEC 62366-1:2015 + AMD1:2020 CSV	Medical devices - Application of usability engineering to medical devices
EN ISO 10993-1:2020	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 11199-3:2005	Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables

NOTE: All Bure XL articles are tested according to the standards listed below instead of IEC 60601-1-2:2007. Other standards mentioned in the table above were applied for XL articles as well.

IEC 60601-1:2005/A1:2012 EN 60601-1:2006 and AMD 1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-6:2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard usability
IEC 60601-1-2:2014 + AMD1:2020	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
IEC 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Appendix II – Product Listing

Description	Article No	Basic UDI
Bure DB Linak, 125 mm	56-303L	7331769045814
Bure DB Linak, 125 mm, US	56-303L-US	7331769047276
Bure DB Linak, 125 mm, handbrakes	56-303L-B/0	7331769043346
Bure DB Linak, 125 mm, handbrakes, PU	56-303L-B/0-PU	7331769043353
Bure DB Linak, 125 mm, handbrakes, PU, UK	56-303L-B/0-PU-UK	7331769043414
Bure DB Linak, 125 mm, handbrakes, UK	56-303L-B/0-UK	7331769043407
Bure DB Linak, 125 mm, PU	56-303L-PU	7331769043339
Bure DB Linak, 125 mm, PU, UK	56-303L-PU-UK	7331769043391
Bure DB Linak, 125 mm, PU, US	56-303L-PU-US	7331769045999
Bure DB Linak, 125 mm, UK	56-303L-UK	7331769043384
Bure DB Linak, 125mm, 1 handbrake	56-303L-B/1	7331769043360
Bure DB Linak, 125mm, 1 handbrake, PU	56-303L-B/1-PU	7331769043377
Bure DB Linak, 125mm, 1 handbrake, PU, UK	56-303L-B/1-PU-UK	7331769043438
Bure DB Linak, 125mm, 1 handbrake, UK	56-303L-B/1-UK	7331769043421
Bure DB Linak, 125mm, AUS	56-303L-AUS	7331769043445
Bure DB Linak, 75 mm	56-303L/75	7331769043452
Bure DB Linak, 75 mm, handbrakes, PU	56-303L/75-B/0-PU	7331769043483
Bure DB Linak, 75 mm, handbrakes, PU, UK	56-303L/75-B/0-PU-UK	7331769043544
Bure DB Linak, 75 mm, UK	56-303L/75-UK	7331769043513
Bure DB Linak, 75mm, 1 handbrake	56-303L/75-B/1	7331769043490
Bure DB Linak, 75mm, 1 handbrake, PU	56-303L/75-B/1-PU	7331769043506
Bure DB Linak, 75mm, 1 handbrake, PU, UK	56-303L/75-B/1-PU-UK	7331769043568
Bure DB Linak, 75mm, 1 handbrake, UK	56-303L/75-B/1-UK	7331769043551
Bure DB Linak, 75mm, handbrakes	56-303L/75-B/0	7331769043476
Bure DB Linak, 75mm, handbrakes, UK	56-303L/75-B/0-UK	7331769043537
Bure DB Linak, 75mm, PU	56-303L/75-PU	7331769043469
Bure DB Linak, 75mm, PU, direction lock	56-303L/75-PU-RS	7331769045692
Bure DB Linak, 75mm, PU, UK	56-303L/75-PU-UK	7331769043520
Bure DB Timotion, 100mm	56-303/100	7331769043230
Bure DB Timotion, 100mm, PU	56-303/100-PU	7331769043247
Bure DB Timotion, 125 mm, 1 handbrake, PU	56-303-B/1-PU	7331769043162
Bure DB Timotion, 125 mm, handbrakes, PU	56-303-B/0-PU	7331769043155
Bure DB Timotion, 125mm, FKN	56-303-FKN_R	7331769042615
Bure DB Timotion, 125mm, Plus	56-303-PLUS	7331769043179
Bure DB Timotion, 125mm, PU	56-303-PU	7331769043193

Description	Article No	Basic UDI
Bure DB Timotion, 125mm, PU, AUS	56-303-PU-AUS	7331769043209
Bure DB Timotion, 125mm, PU, Plus	56-303-PLUS-PU	7331769043186
Bure DB Timotion, 125mm, UK	56-303-UK	7331769043216
Bure DB Timotion, 75 mm, UK	56-303/75-UK	7331769043292
Bure DB Timotion, 75mm	56-303/75	7331769043254
Bure DB Timotion, 75mm, 1 handbrake, FKNW R	56-303/75-B/1-FKNW-R	7331769042592
Bure DB Timotion, 75mm, handbrakes	56-303/75-B/0	7331769043261
Bure DB Timotion, 75mm, handbrakes, PU	56-303/75-B/0-PU	7331769043285
Bure DB Timotion, 75mm, PU	56-303/75-PU	7331769043308
Bure DB Timotion, 75mm, PU, UK	56-303/75-PU-UK	7331769043315
Bure DB Timotion, 125mm	56-303	7331769043117
Bure DB Timotion, 125mm, AUS	56-303-AUS	7331769043124
Bure DB Timotion, 125mm, handbrakes	56-303-B/0	7331769042639
Bure DB Timotion, 125mm, handbrakes, FKHW-R	56-303-B/0-FKHW_R	7331769043131
Bure DB Timotion, 125mm, handbrakes, PU, FKHW-R	56-303-B/0-FKHW_R-PU	7331769043148
Bure DB Timotion, 125mm, TKN	56-303-TKN_R	7331769043223
Bure DB Timotion, 75mm, handbrakes, Plus, FKNW	56-303/75-B/0-FKNW_R-PLUS	7331769043278
Bure DB Timotion, 75mm, TKN	56-303/75-TKN_R	7331769043322
Bure Low Gas, 75mm	56-322/75	7331769045579
Bure Low Linak, 75mm	56-321L/75	7331769045289
Bure Low Linak, 75mm, 1 handbrake	56-321L/75-B/1	7331769045326
Bure Low Linak, 75mm, 1 handbrake, PU	56-321L/75-B/1-PU	7331769045333
Bure Low Linak, 75mm, 1 handbrake, PU, UK	56-321L/75-B/1-PU-UK	7331769045395
Bure Low Linak, 75mm, 1 handbrake, UK	56-321L/75-B/1-UK	7331769045388
Bure Low Linak, 75mm, handbrakes	56-321L/75-B/0	7331769045364
Bure Low Linak, 75mm, handbrakes, PU	56-321L/75-B/0-PU	7331769045319
Bure Low Linak, 75mm, handbrakes, PU, UK	56-321L/75-B/0-PU-UK	7331769045371
Bure Low Linak, 75mm, handbrakes, UK	56-321L/75-B/0-UK	7331769045302
Bure Low Linak, 75mm, PU	56-321L/75-PU	7331769045296
Bure Low Linak, 75mm, PU, UK	56-321L/75-PU-UK	7331769045357
Bure Low Linak, 75mm, UK	56-321L/75-UK	7331769045340
Bure Low S Gas, 125mm	56-322-S	7331769045586
Bure Low S Gas, 125mm, handbrakes	56-322-S-B/0	7331769045593
Bure Low S Gas, 75mm	56-322-S/75	7331769045609
Bure Low S Linak, 125 mm	56-321L-S	7331769045869
Bure Low S Linak, 75mm	56-321L-S/75	7331769045456

Description	Article No	Basic UDI
Bure Low S Linak, 75mm, 1 handbrake	56-321L-S/75-B/1	7331769045494
Bure Low S Linak, 75mm, 1 handbrake, PU	56-321L-S/75-B/1-PU	7331769045500
Bure Low S Linak, 75mm, 1 handbrake, PU, UK	56-321L-S/75-B/1-PU-UK	7331769045562
Bure Low S Linak, 75mm, 1 handbrake, UK	56-321L-S/75-B/1-UK	7331769045555
Bure Low S Linak, 75mm, handbrakes	56-321L-S/75-B/0	7331769045470
Bure Low S Linak, 75mm, handbrakes, PU	56-321L-S/75-B/0-PU	7331769045487
Bure Low S Linak, 75mm, handbrakes, PU, UK	56-321L-S/75-B/0-PU-UK	7331769045548
Bure Low S Linak, 75mm, handbrakes, UK	56-321L-S/75-B/0-UK	7331769045531
Bure Low S Linak, 75mm, PU	56-321L-S/75-PU	7331769045463
Bure Low S Linak, 75mm, PU, UK	56-321L-S/75-PU-UK	7331769045524
Bure Low S Linak, 75mm, UK	56-321L-S/75-UK	7331769045517
Bure Low S Timotion, 100mm	56-321-S/100	7331769045418
Bure Low S Timotion, 125mm	56-321-S	7331769045401
Bure Low S Timotion, 75mm	56-321-S/75	7331769045425
Bure Low S Timotion, 75mm, PU	56-321-S/75-PU	7331769045432
Bure Low S Timotion, 75mm, UK	56-321-S/75-UK	7331769045449
Bure Low Timotion, 125mm	56-321	7331769045258
Bure Low Timotion, 75mm	56-321/75	7331769045265
Bure Low Timotion, 75mm, PU	56-321/75-PU	7331769045272
Bure R&G DB Timotion, PU, Plus, Locked direction	56-309-PLUS-PU-RS	7331769042660
Bure Rise&Go DB Timotion, 125 mm, PU, UK	56-309-PU-UK	7331769044121
Bure Rise&Go DB Linak, 125 mm	56-309L	7331769044336
Bure Rise&Go DB Linak, 125 mm, 1 handbrake	56-309L-B/1	7331769044374
Bure Rise&Go DB Linak, 125 mm, 1 handbrake, PU	56-309L-B/1-PU	7331769044381
Bure Rise&Go DB Linak, 125 mm, 1 handbrake, PU, UK	56-309L-B/1-PU-UK	7331769044459
Bure Rise&Go DB Linak, 125 mm, 1 handbrake, UK	56-309L-B/1-UK	7331769044442
Bure Rise&Go DB Linak, 125 mm, handbrakes	56-309L-B/0	7331769044350
Bure Rise&Go DB Linak, 125 mm, handbrakes, PU	56-309L-B/0-PU	7331769044367
Bure Rise&Go DB Linak, 125 mm, handbrakes, PU, UK	56-309L-B/0-PU-UK	7331769044435
Bure Rise&Go DB Linak, 125 mm, handbrakes, UK	56-309L-B/0-UK	7331769044428
Bure Rise&Go DB Linak, 125 mm, PU	56-309L-PU	7331769044343
Bure Rise&Go DB Linak, 125 mm, PU, UK	56-309L-PU-UK	7331769044411
Bure Rise&Go DB Linak, 125mm, AUS	56-309L-AUS	7331769045623
Bure Rise&Go DB Linak, 125mm, handbrakes, AUS	56-309L-B/0-AUS	7331769044473
Bure Rise&Go DB Linak, 125mm, handbrakes, PU, AUS	56-309L-B/0-PU-AUS	7331769044466
Bure Rise&Go DB Linak, 125mm, PU, direction lock	56-309L-PU-RS	7331769044398

Description	Article No	Basic UDI
Bure Rise&Go DB Linak, 125mm, UK	56-309L-UK	7331769044404
Bure Rise&Go DB Linak, 75 mm, 1 handbrake	56-309L/75-B/1	7331769044527
Bure Rise&Go DB Linak, 75 mm, 1 handbrake, PU	56-309L/75-B/1-PU	7331769044534
Bure Rise&Go DB Linak, 75 mm, handbrakes	56-309L/75-B/0	7331769044503
Bure Rise&Go DB Linak, 75 mm, handbrakes, PU	56-309L/75-B/0-PU	7331769044510
Bure Rise&Go DB Linak, 75mm	56-309L/75	7331769044480
Bure Rise&Go DB Linak, 75mm, 1 handbrake, PU, UK	56-309L/75-B/1-PU-UK	7331769044596
Bure Rise&Go DB Linak, 75mm, 1 handbrake, UK	56-309L/75-B/1-UK	7331769044589
Bure Rise&Go DB Linak, 75mm, handbrakes, PU, UK	56-309L/75-B/0-PU-UK	7331769044572
Bure Rise&Go DB Linak, 75mm, handbrakes, UK	56-309L/75-B/0-UK	7331769044565
Bure Rise&Go DB Linak, 75mm, PU	56-309L/75-PU	7331769044497
Bure Rise&Go DB Linak, 75mm, PU, direction lock	56-309L/75-PU-RS	7331769045630
Bure Rise&Go DB Linak, 75mm, PU, UK	56-309L/75-PU-UK	7331769044558
Bure Rise&Go DB Linak, 75mm, PU, US	56-309L/75-PU-US	7331769047047
Bure Rise&Go DB Linak, 75mm, UK	56-309L/75-UK	7331769044541
Bure Rise&Go DB Timotion, 100mm	56-309/100	7331769044138
Bure Rise&Go DB Timotion, 125 mm, UK	56-309-UK	7331769042608
Bure Rise&Go DB Timotion, 125mm	56-309	7331769044039
Bure Rise&Go DB Timotion, 125mm, AUS	56-309-AUS	7331769044046
Bure Rise&Go DB Timotion, 125mm, handbrakes, PU	56-309-B/0-PU	7331769044077
Bure Rise&Go DB Timotion, 125mm, handbrakes, PU FKNW	56-309-B/0-FKNW_R-PU	7331769044053
Bure Rise&Go DB Timotion, 125mm, handbrakes, PU, Plus, FKHW	56-309-B/0-FKHW_R-PS-PU	7331769044060
Bure Rise&Go DB Timotion, 125mm, Plus	56-309-PLUS	7331769044084
Bure Rise&Go DB Timotion, 125mm, PU	56-309-PU	7331769044107
Bure Rise&Go DB Timotion, 125mm, PU, AUS	56-309-PU-AUS	7331769044114
Bure Rise&Go DB Timotion, 125mm, PU, Plus	56-309-PLUS-PU	7331769044091
Bure Rise&Go DB Timotion, 75mm	56-309/75	7331769044145
Bure Rise&Go DB Timotion, 75mm, AUS	56-309/75-AUS	7331769044152
Bure Rise&Go DB Timotion, 75mm, direction lock, US	56-309/75-US-TRG	7331769044329
Bure Rise&Go DB Timotion, 75mm, FKN	56-309/75-FKN_R	7331769044206
Bure Rise&Go DB Timotion, 75mm, FKNW	56-309/75-FKNW_R	7331769044213
Bure Rise&Go DB Timotion, 75mm, handbrakes	56-309/75-B/0	7331769044169
Bure Rise&Go DB Timotion, 75mm, handbrakes, Plus	56-309/75-B/0-PLUS	7331769044176
Bure Rise&Go DB Timotion, 75mm, handbrakes, PU	56-309/75-B/0-PU	7331769044190

Description	Article No	Basic UDI
Bure Rise&Go DB Timotion, 75mm, handbrakes, PU, Plus	56-309/75-B/0-PS-PU-R	7331769044183
Bure Rise&Go DB Timotion, 75mm, Plus	56-309/75-Plus	7331769044237
Bure Rise&Go DB Timotion, 75mm, PU	56-309/75-PU	7331769044268
Bure Rise&Go DB Timotion, 75mm, PU, AUS	56-309/75-PU-AUS	7331769044275
Bure Rise&Go DB Timotion, 75mm, PU, FKNW	56-309/75-FKNW_R-PU	7331769044220
Bure Rise&Go DB Timotion, 75mm, PU, Plus	56-309/75-PLUS-PU	7331769044244
Bure Rise&Go DB Timotion, 75mm, PU, Plus, UK	56-309/75-PLUS-PU-UK	7331769044251
Bure Rise&Go DB Timotion, 75mm, PU, UK	56-309/75-PU-UK	7331769044282
Bure Rise&Go DB Timotion, 75mm, PU, US	56-309/75-PU-US	7331769044299
Bure Rise&Go DB Timotion, 75mm, TKN	56-309/75-TKN_R	7331769044305
Bure Rise&Go DB Timotion, 75mm, UK	56-309/75-UK	7331769044312
Bure S Gas, 125 mm	56-301	7331769042752
Bure S Gas, 125 mm, handbrakes	56-301-B/0	7331769042769
Bure S Gas, 125mm, PU	56-301-PU	7331769042776
Bure S Gas, 75mm	56-301/75	7331769042783
Bure S Gas, 75mm, handbrakes	56-301/75-B/0	7331769045951
Bure S Gas, 75mm, locked direction	56-301/75-RS	7331769042806
Bure S Gas, 75mm, PU	56-301/75-PU	7331769042790
Bure S Linak, 125 mm	56-302L	7331769045760
Bure S Linak, 125 mm, UK	56-302L-UK	7331769042813
Bure S Linak, 125mm, 1 handbrake	56-302L-B/1	7331769045746
Bure S Linak, 125mm, 1 handbrake, PU	56-302L-B/1-PU	7331769042646
Bure S Linak, 125mm, 1 handbrake, PU, UK	56-302L-B/1-PU-UK	7331769042868
Bure S Linak, 125mm, 1 handbrake, UK	56-302L-B/1-UK	7331769042851
Bure S Linak, 125mm, handbrakes	56-302L-B/0	7331769042622
Bure S Linak, 125mm, handbrakes, PU	56-302L-B/0-PU	7331769045838
Bure S Linak, 125mm, handbrakes, PU, UK	56-302L-B/0-PU-UK	7331769042844
Bure S Linak, 125mm, handbrakes, UK	56-302L-B/0-UK	7331769042837
Bure S Linak, 125mm, PU	56-302L-PU	7331769045753
Bure S Linak, 125mm, PU, UK	56-302L-PU-UK	7331769042820
Bure S Linak, 75mm, 1 handbrake	56-302L/75-B/1	7331769042936
Bure S Linak, 75mm, 1 handbrake, PU	56-302L/75-B/1-PU	7331769042943
Bure S Linak, 75mm, 1 handbrake, PU, UK	56-302L/75-B/1-PU-UK	7331769043001
Bure S Linak, 75mm, 1 handbrake, UK	56-302L/75-B/1-UK	7331769042998
Bure S Linak, 75mm, handbrakes	56-302L/75-B/0	7331769042912
Bure S Linak, 75mm, handbrakes, PU	56-302L/75-B/0-PU	7331769042929

Description	Article No	Basic UDI
Bure S Linak, 75mm, handbrakes, PU, UK	56-302L/75-B/0-PU-UK	7331769042981
Bure S Linak, 75mm, handbrakes, UK	56-302L/75-B/0-UK	7331769042974
Bure S Linak, 75mm, PU	56-302L/75-PU	7331769042905
Bure S Linak, 75mm, PU, UK	56-302L/75-PU-UK	7331769042967
Bure S Linak, 75mm, UK	56-302L/75-UK	7331769042950
Bure S Manual, 100mm	56-300/100	7331769042691
Bure S Manual, 125 mm	56-300	7331769045821
Bure S Manual, 125 mm, 1 handbrake	56-300-B/1	7331769045784
Bure S Manual, 125 mm, handbrakes	56-300-B/0	7331769045807
Bure S Manual, 75mm	56-300/75	7331769045715
Bure S Manual, 75mm, 1 handbrake, PU	56-300/75-B/1-PU	7331769042745
Bure S Manual, 75mm, handbrakes	56-300/75-B/0	7331769042721
Bure S Manual, 75mm, handbrakes, PU	56-300/75-B/0-PU	7331769042738
Bure S Manual, 75mm, locked direction	56-300/75-DIR	7331769042714
Bure S Timotion, 125mm	56-302T	7331769043018
Bure S Timotion, 125mm, FKN	56-302T-FKN_R	7331769043063
Bure S Timotion, 125mm, PU	56-302T-PU	7331769043025
Bure S Timotion, 125mm, TK	56-302T-TK	7331769043056
Bure S Timotion, 125mm, UK	56-302T-UK	7331769043032
Bure S Timotion, 75mm	56-302T/75	7331769043070
Bure S Timotion, 75mm, FKN	56-302T/75-FKN_R	7331769043100
Bure S Timotion, 75mm, PU	56-302T/75-PU	7331769043087
Bure S Timotion, 75mm, PU, AUS	56-302T/75-PU-AUS	7331769043094
Bure S Timotion, handbrakes	56-302T-B/0	7331769043049
Bure S, Linak, 125mm, AUS	56-302L-AUS	7331769042882
Bure S, Linak, 125mm, US	56-302L-US	7331769042875
Bure S, Linak, 75mm	56-302L/75	7331769042899
Bure Space Gas Low, 125 mm	56-307/LOW	7331769042394
Bure Space Gas, 100mm	56-307/100	7331769044015
Bure Space Gas, 125mm	56-307	7331769043988
Bure Space Gas, 125mm, 1 handbrake, PU	56-307-B/1-PU	7331769044008
Bure Space Gas, 125mm, PU	56-307-PU	7331769043995
Bure Space Gas, 75mm	56-307/75	7331769044022
Bure Space Gas, 75mm, handbrakes, PU	56-307/75-B/0-PU	7331769042684
Bure Space Gas, 75mm, PU	56-307/75-PU	7331769042677
Bure Space Linak, 125 mm	56-304L	7331769045791

Description	Article No	Basic UDI
Bure Space Linak, 125 mm, 1 handbrake	56-304L-B/1	7331769043773
Bure Space Linak, 125 mm, 1 handbrake, PU	56-304L-B/1-PU	7331769043780
Bure Space Linak, 125 mm, 1 handbrake, PU, UK	56-304L-B/1-PU-UK	7331769043841
Bure Space Linak, 125 mm, 1 handbrake, UK	56-304L-B/1-UK	7331769043834
Bure Space Linak, 125 mm, handbrakes	56-304L-B/0	7331769043759
Bure Space Linak, 125 mm, handbrakes, PU	56-304L-B/0-PU	7331769043766
Bure Space Linak, 125 mm, handbrakes, PU, UK	56-304L-B/0-PU-UK	7331769043827
Bure Space Linak, 125 mm, handbrakes, UK	56-304L-B/0-UK	7331769043810
Bure Space Linak, 125 mm, PU	56-304L-PU	7331769043742
Bure Space Linak, 125 mm, UK	56-304L-UK	7331769043797
Bure Space Linak, 125mm, PU, UK	56-304L-PU-UK	7331769043803
Bure Space Linak, 75 mm, 1 handbrake	56-304L/75-B/1	7331769043902
Bure Space Linak, 75 mm, 1 handbrake, PU	56-304L/75-B/1-PU	7331769043919
Bure Space Linak, 75 mm, 1 handbrake, PU, UK	56-304L/75-B/1-PU-UK	7331769043971
Bure Space Linak, 75 mm, 1 handbrake, UK	56-304L/75-B/1-UK	7331769043964
Bure Space Linak, 75 mm, handbrakes	56-304L/75-B/0	7331769043889
Bure Space Linak, 75 mm, handbrakes, PU	56-304L/75-B/0-PU	7331769043896
Bure Space Linak, 75 mm, handbrakes, PU, UK	56-304L/75-B/0-PU-UK	7331769043957
Bure Space Linak, 75 mm, handbrakes, UK	56-304L/75-B/0-UK	7331769043940
Bure Space Linak, 75mm	56-304L/75	7331769043858
Bure Space Linak, 75mm, PU	56-304L/75-PU	7331769043865
Bure Space Linak, 75mm, PU, direction lock	56-304L/75-PU-RS	7331769043872
Bure Space Linak, 75mm, PU, UK	56-304L/75-PU-UK	7331769043933
Bure Space Linak, 75mm, UK	56-304L/75-UK	7331769043926
Bure Space Timotion, 100mm	56-304/100	7331769043667
Bure Space Timotion, 100mm, PU, Plus	56-304/100-PU-PLUS	7331769043674
Bure Space Timotion, 125 mm	56-304	7331769043575
Bure Space Timotion, 125mm, 1 handbrake, PU, Plus	56-304-B/1-PL-PU	7331769043612
Bure Space Timotion, 125mm, handbrakes, FKN	56-304-B/0-FKN_R	7331769043636
Bure Space Timotion, 125mm, handbrakes, PU	56-304-B/0-PU	7331769043629
Bure Space Timotion, 125mm, handbrakes, PU, FKH	56-304-B/0-FKH_R-PU	7331769043643
Bure Space Timotion, 125mm, handbrakes, PU, Plus, FKH	56-304-B/0-FKH_R-PL-PU-R	7331769043650
Bure Space Timotion, 125mm, Plus	56-304-PLUS	7331769043605
Bure Space Timotion, 125mm, PU	56-304-PU	7331769043582
Bure Space Timotion, 125mm, PU, Plus	56-304-PLUS-PU	7331769043599
Bure Space Timotion, 75mm	56-304/75	7331769043681

Description	Article No	Basic UDI
Bure Space Timotion, 75mm, 1 handbrake	56-304/75-B/1	7331769043728
Bure Space Timotion, 75mm, handbrakes	56-304/75-B/0	7331769043735
Bure Space Timotion, 75mm, handbrakes, PU, FKH	56-304/75-B/0-FKH_R-PS-PU	7331769042363
Bure Space Timotion, 75mm, handbrakes, PU, FKN	56-304/75-B/0-FKN_R-PU	7331769042370
Bure Space Timotion, 75mm, Plus	56-304/75-PLUS	7331769043704
Bure Space Timotion, 75mm, PU	56-304/75-PU	7331769043698
Bure Space Timotion, 75mm, PU, Plus	56-304/75-PLUS-PU	7331769043711
Bure Std Gas, 100mm	56-311/100	7331769044718
Bure Std Gas, 100mm, PU	56-311/100-PU	7331769044725
Bure Std Gas, 125mm	56-311	7331769044657
Bure Std Gas, 125mm, 1 direction lock	56-311-RS	7331769044701
Bure Std Gas, 125mm, 1 handbrake	56-311-B/1	7331769044671
Bure Std Gas, 125mm, handbrakes, PU	56-311-BRAKE/0-PU	7331769044688
Bure Std Gas, 125mm, KnockDown, 2 direction locks	56-311-PARSONS-KD	7331769044664
Bure Std Gas, 125mm, PU	56-311-PU	7331769044695
Bure Std Gas, 75mm	56-311/75	7331769044732
Bure Std Gas, 75mm, 1 handbrake	56-311/75-B/1	7331769044756
Bure Std Gas, 75mm, handbrakes	56-311/75-B/0	7331769044749
Bure Std Gas, 75mm, PU	56-311/75-PU	7331769044763
Bure STD Linak 75mm, AUS	56-312L/75-AUS	7331769045166
Bure STD Linak, 125 mm	56-312L	7331769044879
Bure STD Linak, 125mm, 1 handbrake	56-312L-B/1	7331769044916
Bure STD Linak, 125mm, 1 handbrake, PU	56-312L-B/1-PU	7331769044923
Bure STD Linak, 125mm, 1 handbrake, PU, UK	56-312L-B/1-PU-UK	7331769044985
Bure STD Linak, 125mm, 1 handbrake, UK	56-312L-B/1-UK	7331769044978
Bure STD Linak, 125mm, AUS	56-312L-AUS	7331769045036
Bure STD Linak, 125mm, handbrakes	56-312L-B/0	7331769044893
Bure STD Linak, 125mm, handbrakes, PU	56-312L-B/0-PU	7331769044909
Bure STD Linak, 125mm, handbrakes, PU, UK	56-312L-B/0-PU-UK	7331769044961
Bure STD Linak, 125mm, handbrakes, UK	56-312L-B/0-UK	7331769044954
Bure STD Linak, 125mm, Knockdown	56-312L-KD	7331769045005
Bure STD Linak, 125mm, Knockdown Aus	56-312L-KD-AUS	7331769045012
Bure STD Linak, 125mm, Knockdown CAN	56-312L-CAN-KD	7331769044992
Bure STD Linak, 125mm, Knockdown US	56-3123L-KD-US	7331769046965
Bure STD Linak, 125mm, PU	56-312L-PU	7331769044886
Bure STD Linak, 125mm, PU, UK	56-312L-PU-UK	7331769044947

Description	Article No	Basic UDI
Bure STD Linak, 125mm, UK	56-312L-UK	7331769044930
Bure STD Linak, 125mm, US	56-312L-US	7331769045029
Bure STD Linak, 75mm	56-312L/75	7331769045043
Bure STD Linak, 75mm, 1 handbrake	56-312L/75-B/1	7331769045081
Bure STD Linak, 75mm, 1 handbrake, PU	56-312L/75-B/1-PU	7331769045098
Bure STD Linak, 75mm, 1 handbrake, PU, UK	56-312L/75-B/1-PU-UK	7331769045159
Bure STD Linak, 75mm, 1 handbrake, UK	56-312L/75-B/1-UK	7331769045142
Bure STD Linak, 75mm, handbrakes	56-312L/75-B/0	7331769045067
Bure STD Linak, 75mm, handbrakes, PU	56-312L/75-B/0-PU	7331769045074
Bure STD Linak, 75mm, handbrakes, PU, UK	56-312L/75-B/0-PU-UK	7331769045135
Bure STD Linak, 75mm, handbrakes, UK	56-312L/75-B/0-UK	7331769045128
Bure STD Linak, 75mm, PU	56-312L/75-PU	7331769045050
Bure STD Linak, 75mm, PU, UK	56-312L/75-PU-UK	7331769045111
Bure STD Linak, 75mm, UK	56-312L/75-UK	7331769045104
Bure Std Manual, 100mm	56-310/100	7331769044626
Bure Std Manual, 125mm, PU	56-310-PU	7331769046026
Bure Std Manual, 125mm	56-310	7331769044602
Bure Std Manual, 125mm, handbrakes	56-310-B/0	7331769044619
Bure Std Manual, 125mm, KnockDown	56-310-PARSONS-KD	7331769045777
Bure Std Manual, 75mm	56-310/75	7331769044633
Bure Std Manual, 75mm, handbrakes	56-310/75-B/0	7331769044640
Bure Std Timotion, 100mm	56-312T/100	7331769044848
Bure Std Timotion, 125mm	56-312T	7331769044770
Bure Std Timotion, 125mm, handbrakes	56-312T-BRAKE/0	7331769044794
Bure Std Timotion, 125mm, handbrakes, PU	56-312T-B/0-PU	7331769044787
Bure Std Timotion, 125mm, handbrakes, TK	56-312T-B/0-TKN_R	7331769044800
Bure Std Timotion, 125mm, PU	56-312T-PU	7331769044817
Bure Std Timotion, 125mm, TK	56-312T-TK	7331769044824
Bure Std Timotion, 125mm, US	56-312T-US	7331769044831
Bure Std Timotion, 75mm	56-312T/75	7331769044855
Bure Std Timotion, 75mm, handbrakes	56-312T/75-B/0	7331769042707
Bure Std Timotion, 75mm, PU	56-312T/75-PU	7331769044862
Bure XL, 100mm	56-315/100	7331769042400
Bure XL, 125mm	56-315	7331769045173
Bure XL, 125mm, 1 handbrake	56-315-B/1	7331769045227
Bure XL, 125mm, AUS	56-315-AUS	7331769045616

Description	Article No	Basic UDI
Bure XL, 125mm, handbrakes	56-315-B/0	7331769045203
Bure XL, 125mm, handbrakes, PU	56-315-B/0-PU	7331769045210
Bure XL, 125mm, PU	56-315-PU	7331769045180
Bure XL, 125mm, UK	56-315-UK	7331769045197
Bure XL, 75mm	56-315/75	7331769045234
Bure XL, 75mm, PU	56-315/75-PU	7331769045241
Bure XL, 75mm, handbrakes, PU	56-315/75-B/0-PU	7331769046347

Appendix II – Product Listing

The following articles are accessories to the Walkers:

Description	Article No	Basic UDI
Uppresningssele Multi M, Bure	56-324-M	7350013324017
Uppresningssele Multi L, Bure	56-324-L	7350013324024
Uppresningssele Multi S, Bure	56-324-S	7350013324031
Uppresningssele Multi XL, Bure	56-324-XL	7350013324048
Fastsättningsrem Multi, Bure	56-324-1	7350013324055
Gåträningssats Multi, Bure	56-324-2	7350013324062
Ståplatta till Bure Double	56-325	7350013325014
Hälband till ståplatta	58-328-1	7350013583285
Elmotorsats (EU)/TiMotion Bure el höj/sänk	56-332T	7350013563225
Ståplatta Kort/2015 Bure DB, Rise DB	56-333-DB	7350013333033
Ståplatta Kort/2015, SW, Bure DB, Rise DB	56-333/SW-DB	7350013333071
Ståplatta Kort/2015 Bure Std, S, Rise	56-333-STD	7350013333040
Ståplatta Kort/2015, SW, Bure Std, S, Rise	56-333/SW-STD	7350013333088
Syrgastubshållare	56-336-4	7331769042042
Droppstång, Bure	56-334	7350013563348
Droppstång, Bure, komplett	56-338	7350013563386
Sidostöd (4-knt), Bure	56-337	7350013633713
Sidostöd (4-knt) PUR-kudde, Bure	56-337-PU	7350013633720
Handbromstillrats/2016, 2 Bromshtg, Bure Std, Low, Ortho, Space, XL	56-339-1-0	7350013339011
Handbromstillrats/2016, Enhandsbroms, Bure Std, Low, Ortho, Space, XL	56-339-1-1	7350013339028
Handbromstillrats/2016, 2 Bromshtg, Bure DB 2.0	56-339-2-0	7350013339035
Handbromstillrats/2016, Enhandsbroms, Bure DB 2.0	56-339-2-1	7350013339042
Handbromstillrats/2016, 2 Bromshtg, Bure Rise & Go,	56-339-3-0	7350013339059
Handbromstillrats/2016, Enhandsbroms, Bure Rise & Go	56-339-3-1	7350013339066
Handbromstillrats/2016, 2 Bromshtg, Bure Rise & Go DB	56-339-4-0	7350013339073
Handbromstillrats/2016, Enhandsbroms, Bure Rise & Go DB	56-339-4-1	7350013339080
Handbromstillrats/2016, 75mm hjul, 2 Bromshtg, Bure Std	56-339/75-1-0	7350013339097
Handbromstillrats/2016, 75mm hjul, Enhandsbroms, Bure Std	56-339/75-1-1	7350013339103

Description	Article No	Basic UDI
Handbromstillrats/2016, 75mm hjul, 2 Bromshtg, Bure DB 2.0	56-339/75-2-0	7350013339110
Handbromstillrats/2016, 75mm hjul, Enhandsbroms, Bure DB 2.0	56-339/75-2-1	7350013339127
Handbromstillrats/2016, 75mm hjul, 2 Bromshtg, Bure Rise & Go	56-339/75-3-0	7350013339134
Handbromstillrats/2016, 75mm hjul, 2 Bromshtg, Bure Rise & Go DB	56-339/75-4-0	7350013339158
Handbromstillrats/2016, 75mm hjul, Enhandsbroms, Bure Rise & Go DB	56-339/75-4-1	7350013339165
Underbensstöd, Bure	56-352	7331769047795
Körhandtag standard	57-368	7331769047801
Ståplatta Lång/2015 Bure DB, Rise DB	56-383-DB	7350013383021
Ståplatta Lång/2015, SW, Bure DB, Rise DB	56-383/SW-DB	7350013383069
Ståplatta Lång/2015, SW, Bure DB, Rise DB, Italy	56-383/SW-DB-ITA	7350013383090
Ståplatta Lång/2015 Bure Std, Rise, S	56-383-STD	7350013383038
Ståplatta Lång/2015, SW, Bure Std, Rise, S	56-383/SW-STD	7350013383076
Uppresningssele "MULTI" L, Rise&Go	56-384-MULTI-L	7350013384059
Uppresningssele "MULTI" M, Rise&Go	56-384-MULTI-M	7350013384066
Uppresningssele "MULTI" S, Rise&Go	56-384-MULTI-S	7350013384073
Uppresningssele "MULTI" XL, Rise&Go	56-384-MULTI-XL	7350013384080
Uppresningssele "MULTI" XS, Rise&Go	56-384-MULTI-XS	7350013384097
Gåträningssele Sadel inkl. fästen (4st), Bure Std	56-388	7350013388088
Gåträningskit inkl fästen/Multi, Rise&Go	56-388-KIT	7350013388064
Mjukkorg m fäste Bure	56-389	7331769047818
Serveringsbricka inkl. hållare, Bure	56-393	7331769047825
Htg FK (Upp/Ned) Normal speed	58-387-1	7350013838712
Htg FK (Upp/Ned) High speed	58-387-2	7350013838729
Htg FK Breddning	58-387-3	7350013838736
Set Htg TK (Upp/Ned) Normal speed	58-388-1	7350013838811
Set Htg TK (Upp/Ned) High speed	58-388-2	7331769047832
Set Htg TK Breddning	58-388-3	7331769047849
Körhandtag till Rise/Go Double	57-391	7331769047856
Bakre enhet inkl hjul, Handbroms Bure	58-395-STD	7350013395017
Handbromstillrats/2016, 75mm hjul, Enhandsbroms, Bure Rise & Go	56-339/75-3-1	7331769042417
Armstöds kudde Låg Vänster, Bure	57-357-L	7331769042448
Armstöds kudde Låg Höger, Bure	57-357-R	7331769042455

Description	Article No	Basic UDI
Armstödsplatta höger Bure XL	56-378	7350013563782
Armstödsplatta vänster Bure XL	56-379	7350013563799
Armstödsplattor PU PAR, Bure Std, Double 2.0, Low, S, Space, XL	57-361-PAR	7331769047863
Ståplatta låg, Bure Double	56-325-LOW	7350013325038

Revision log

Version	Date	Amendment
1.0	2021-05-24	First issue for MDR compliance
2.0		Unknown changes
3.0		Unknown changes
4.0	2022-02-24	<ul style="list-style-type: none">• XL and SPACE products are added.• Clarification for XL testing was added, see NOTE after the first table• GMDN is corrected.
5.0	2022-12-08	Amended product configurations, removed GMDN.
6.0	2023-01-31	Added configuration 56-303L-PU-US for the US market.
7.0	2024-10-09	General review: <ul style="list-style-type: none">• Removed obsolete accessories• Corrected typos• Added configurations