

EU Declaration of Conformity

Manufacturer:

Foshan Dongfang Medical Equipment Manufactory
(LTD.)
5 Xingfu Road, Zone A, Shishan Industrial Park,
Nanhai District, Foshan City, P.R. China, 528000

SRN: CN-MF-000036028

whose single Authorized Representative:

MedNet EC-Rep GmbH
Borkstrasse 10. 48163 Muenster. Germany

SRN: DE-AR-000000002

We, the manufacturer, herewith declare that the products

WALKING AIDS AND ACCESSORIES

Model: List in attachment

Trade Name: MCM, EUROMIX, FS, SILFAB, FOSHAN

UMDNS-Code: **14393**

meet the provisions of Regulation (EU)2017/745 which apply to them.

The medical device has been assigned to class I according to ANNEX VIII, rule 1 of (EU)2017/745. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex IV of (EU)2017/745.

conformity assessment: Annex II, Annex III of EU 2017/745.

Applied Standards:

EN ISO13485:2016 Quality system-medical instruments

EN ISO 14971:2019 Risk analysis of medical instruments

ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements

EN ISO 14155:2020 Clinical investigation of medical devices for human subjects -- Good clinical practice

EN 1985:1998 Walking aids. General requirements and test methods

EN ISO 11199-1:2021 Walking aids manipulated by both arms -- Requirements and test methods -- Part 1: Walking frames

EN ISO 11199-2:2005 Walking aids manipulated by both arms -- Requirements and test methods -- Part 2: Rollators

ISO 11334-1:2007 Assistive products for walking manipulated by one arm -- Requirements and test methods -- Part 1: Elbow crutches

ISO 11334-4:1999 Walking aids manipulated by one arm. Requirements and test methods. Part 4: Walking sticks with three or more legs

ISO 10289:1999 Methods for corrosion testing of metallic and other inorganic coatings on metallic substrates - Rating of test specimens and manufactured articles subjected to corrosion tests

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Foshan Dongfang Medical Equipment Manufactory (LTD.)
 Address: 5 Xingfu Road, Zone A, Shishan Industrial Park, Nanhai District,
 Foshan City, P.R. China, 528000

佛山市东方医疗设备厂有限公司
 FOSHAN DONGFANG MEDICAL
 EQUIPMENT MANUFACTORY(LTD.)

N.V. 22. 2023
 Place, date

[Signature]
 Legally binding signature, Function

Product	Model(s)
Walker	FS201, FS203, FS9121L-A, FS9122L, FS9122L-A, FS9123L, FS9123L(S)-B, FS9124L, FS9125L, FS9126L, FS9128L, FS912L, FS912L(XS), FS9131L, FS9133L, FS9134L, FS913L, FS9142L, FS9145L, FS914H-1, FS914L, FS9151L, FS9152L, FS9153L, FS915L, FS917L (L, M, S), FS918L, FS919L, FS9610, FS9611, FS9612, FS9613, FS961L, FS962, FS9621, FS9622, FS9631L, FS9632L, FS9634L, FS9635L, FS9636L, FS9637L, FS963L, FS9671L, FS967L
Walking stick	FS910L, FS9111L, FS9112L, FS911L, FS9203L, FS9204L, FS9206L, FS9207LW-1, FS9207LW-2, FS9207LW-3, FS9208L, FS920L, FS921, FS9212L, FS921L, FS922, FS9221, FS924, FS9242L, FS9243, FS924L, FS926, FS9274L, FS9276L (13), FS927L, FS9280L, FS9281L, FS928L, FS929L, FS9300L, FS9301L-4, FS9301L, FS9301L-1, FS9301L-2, FS9301L-3, FS9304L, FS9306L, FS9306L (14), FS930L, FS931, FS931L, FS932, FS9321, FS9322, FS934, FS9361L, FS936L, FS9381L, FS9382L, FS938L (12), FS9391L, FS939L, FS941, FS9411L, FS9412L, FS9413L, FS9414L, FS9415L, FS942S, FS943L, FS945, FS945L, FS946A, FS946S, FS947, FS948L, FS949L, FS580, FS581, FS582, FS583, FS5915
Elbow crutch	FS923L, FS9331L, FS9332L, FS933L, FS933L-A, FS937L
Crutch	FS9251L(L), FS9251L(M), FS9251L(S), FS9252L, FS9256L(L), FS9256L(M), FS9256L(S), FS925L(L), FS925L(M), FS925L(S), FS925LA, FS925LB, FS925LC, FS935(L), FS935(M), FS935(S), FS935S (L, M, S)
Rollator	FS9650LH, FS965LH, FS965LH-1, FS965LH-B, FS9650LH, FS965LH, FS965LH-1, FS965LH-B, FS969H, FS965LHF1, FS965LH1
Pedal exercise	FS960, FS9600, FS9601, FS9602
Accessories	01L, 03L, 04L, 05L, 06L, 07L, 08L, D43, D44, D45, D46, D47, D48, D49, D50, D51, D52, D53, D54, D55, D56, D57, D58, D59, D60, D61, D62, D63, D64, D65, F01, F02, F03, F04, F05, F06, F07, F08, F09, F10, F11, F12, F13, F14, F15, F16

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MODEL	BASIC UDI-DI
FS5311	6938001012927
FS201	6938001022186
FS203	6938001022193
FS9121L-A	6938001022209
FS9122L	6938001020465
FS9122L-A	6938001021165
FS9123L	6938001020472
FS9123L(S)-B	6938001021271
FS9124L	6938001022216
FS9125L	6938001021158
FS9126L	6938001022223
FS9128L	6938001022230
FS912L	6938001020137
FS912L(XS)	6938001022247
FS9131L	6938001020793
FS9133L	6938001022254
FS9134L	6938001022261
FS913L	6938001020038
FS9142L	6938001022278
FS9145L	6938001021141
FS914H-1	6938001022285
FS914L	6938001021202
FS9151L	6938001022292
FS9152L	6938001022308
FS9153L	6938001022315
FS915L	6938001020304
FS917L(L)	6938001022322
FS917L(M)	6938001022339
FS917L(S)	6938001022346
FS919L	6938001020427
FS9610	6938001022353
FS9611	6938001022360
FS9612	6938001021097
FS9613	6938001022377
FS961L	6938001020328
FS962	6938001022384
FS9621	6938001022391
FS9622	6938001022407
FS9631L	6938001020687
FS9632L	6938001020397

FS918L	6938001021257
FS9634L	6938001022414
FS9635L	6938001022421
FS9636L	6938001022438
FS9637L	6938001022445
FS963L	6938001021110
FS9671L	6938001022452
FS967L	6938001022469
FS910L	6938001020441
FS9111L	6938001022629
FS9112L	6938001022636
FS911L	6938001020212
FS9203L	6938001022643
FS9204L	6938001022650
FS9206L	6938001022667
FS9207LW-1	6938001021226
FS9207LW-2	6938001022674
FS9207LW-3	6938001022681
FS920L	6938001020236
FS921	6938001020267
FS9212L	6938001022704
FS921L	6938001020861
FS922	6938001020168
FS9221	6938001022711
FS924	6938001020052
FS9242L	6938001022728
FS9243	6938001022735
FS924L	6938001020779
FS926	6938001020618
FS9274L	6938001022742
FS9276L(13)	6938001022759
FS927L	6938001020175
FS9280L	6938001022766
FS9281L	6938001022773
FS928L	6938001022780
FS929L	6938001020458
FS9300L	6938001022797
FS9301L-4	6938001022803
FS9301L	6938001022810
FS9301L-1	6938001022827
FS9301L-2	6938001022834

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FS9208L	6938001022698
FS9301L-3	6938001022841
FS9304L	6938001022858
FS9306L	6938001022865
FS9306L(14)	6938001022872
FS930L	6938001020069
FS931	6938001021103
FS931L	6938001022889
FS932	6938001020182
FS9321	6938001022896
FS9322	6938001022902
FS934	6938001020847
FS9361L	6938001022919
FS936L	6938001020205
FS9381L	6938001022926
FS9382L	6938001022933
FS938L(12)	6938001022940
FS9391L	6938001022957
FS941	6938001022964
FS9411L	6938001022971
FS9412L	6938001022988
FS9413L	6938001022995
FS9414L	6938001023008
FS9415L	6938001023015
FS942S	6938001020434
FS943L	6938001020830
FS945	6938001023022
FS945L	6938001023039
FS946A	6938001023046
FS946S	6938001023053
FS947	6938001020786
FS948L	6938001023060
FS949L	6938001021172
FS580	6938001023077
FS9251L(L)	6938001022513
FS9251L(M)	6938001022520
FS9251L(S)	6938001022537
FS9252L	6938001022544
FS9256L(L)	6938001022551
FS9256L(M)	6938001022568
FS9256L(S)	6938001022575
FS939L	6938001020243

FS925L(L)	6938001020571
FS925L(M)	6938001020564
FS925L(S)	6938001020557
FS925LA	6938001022582
FS925LB	6938001022599
FS925LC	6938001022605
FS935(L)	6938001020601
FS935(M)	6938001020595
FS935(S)	6938001020588
FS935S(L)	6938001022612
FS9650LH	6938001023312
FS965LH	6938001020342
FS965LH-1	6938001023329
FS965LH-B	6938001023336
FS9650LH	6938001023343
FS965LH	6938001020342
FS965LH-1	6938001023350
FS965LH-B	6938001023336
FS960	6938001020311
FS9600	6938001023374
FS9601	6938001023381
FS9602	6938001023398
FS923L	6938001022476
FS9331L	6938001022483
FS9332L	6938001022490
FS933L	6938001020274
FS933L-A	6938001022506
FS937L	6938001020250
01L	6938001030082
03L	6938001030082
04L	6938001030082
05L	6938001030082
06L	6938001030082
07L	6938001030082
08L	6938001030082
D43	6938001030082
D44	6938001030082
D45	6938001030082
D46	6938001030082
D47	6938001030082
D48	6938001030082
D49	6938001030082

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D50	6938001030082
D51	6938001030082
D52	6938001030082
D53	6938001030082
D54	6938001030082
D55	6938001030082
D56	6938001030082
D57	6938001030082
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F09	6938001030082
F10	6938001030082
F11	6938001030082
F12	6938001030082
F13	6938001030082
F14	6938001030082
F15	6938001030082
F16	6938001030082
FS969H	6938001023312
FS965LHF1	6938001023312
FS965LH1	6938001023312

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