

EC Declaration of Conformity

Manufacturer:

Foshan Dongfang Medical Equipment
Manufactory (LTD.)
SRN:NOT YET

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

Basic UDI(GMN):69380010003QM

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

FOSHAN DONGFANG MEDICAL
EQUIPMENT MANUFACTORY(LTD)



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AUTHORIZED SIGNATURE

FOSHAN, 2021-6-30

SUNNY LEANG, VICE MANAGER

Place, date

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