



Declaration of Conformity

Name & Address of the Manufacturer: Trulife Limited, 41 Amos Road, Sheffield, S9 1BX, UK

EU Authorised Representative: MDSS, Schiffgraben 41, 30175, Hannover, Germany

SRN: GB-MF-000015741

Name of Device(s): Walking frames

Product Code: See Annex I attached

Reference Number: See Annex I attached

Basic UDI-DI: 5052893WAFEX

Intended Use: These devices are designed to provide support, stability and help with mobilisation of people with walking difficulties and disabilities.

Classification: Class 1 Rule 1

Certified Standards used:

11199-1 1999	Walking aids manipulated by both arms requirements and test methods (Walking frames)
11199-2 2005	Walking aids manipulated by both arms Requirements and test methods (Rollators)
24415-1 2009	Tips for assistive products for walking Requirements and test methods. (Friction of tips)

Conformity Assessment (CE): Trulife complies with Annex II and Annex III according to Regulation MDR 2017/745 for CE Labelling of their products

Conformity Assessment (UKCA): Trulife complies with Annex VII of Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC and its transposition in UK 'The Medical Devices Regulations 2002'

Declaration:

This declaration of conformity is issued under the sole responsibility of Trulife. We hereby declare that the medical device(s) specified above meet the provision of the Regulation MDR 2017/745 for medical devices and Medical Device Directive 93/42/EEC as transposed into UK law 'The Medical Devices Regulations 2002'.

This declaration is supported by the Quality System approval to ISO 13485:2016 issued by LRQA. All supporting documentation is retained at the premises of the legal manufacturer.

Signed by:

Name:

H. Longden

Date Issued:

24th December 2021

Position:

General Manager

Place of Issue

Sheffield, UK

Annex I

Code	Description	UDI
RJ790100	Childs Walking Frame GOLD Coated Non-Wheeled	5052893002000
RJ790200	Childs Walking Frame GREEN Coated Non-Wheeled	5052893002017
RJ790300	Childs Walking Frame - Non-Wheeled	5052893002031
RJ790600	Childs Walking Frame GOLD Coated Wheeled	5052893001997
RJ790700	Childs Walking Frame GREEN Coated Wheeled	5052893002024
RJ790800	Childs Walking Frame - Wheeled	5052893002048
RM551572	Compact Adjustable Height Frame 72-82cm	5052893000006
RM551579	Compact Adjustable Height Frame 79-89cm	5052893000013
RM551587	Compact Adjustable Height Frame 87-97cm	5052893000020
RM551595	Compact Adjustable Height Frame 95-105cm	5052893000037
RM552072	Slimline Adjustable Height Frame 72-82cm	5052893000044
RM552079	Slimline Adjustable Height Frame 79-89cm	5052893000051
RM552087	Slimline Adjustable Height Frame 87-97cm	5052893000068
RM552666	Hospital Adjustable Height Frame 66-73cm	5052893000075
RM552676	Hospital Adjustable Height Frame 76-83cm	5052893000082
RM552686	Hospital Adjustable Height Frame 86-93cm	5052893000099
RM553572	Domestic Adjustable Height Frame 72-82cm	5052893000105
RM553579	Domestic Adjustable Height Frame 79-89cm	5052893000112
RM553579/RED	Domestic Adjustable Height Frame 79-89cm RED	5052893002093
RM553587	Domestic Adjustable Height Frame 87-97cm	5052893000129
RM553587/RED	Domestic Adjustable Height Frame 87-97cm RED	5052893002109
RM563073	Compact Adjustable Height Wheeled Frame 73-83cm	5052893000136
RM563080	Compact Adjustable Height Wheeled Frame 80-90cm	5052893000143
RM563088	Compact Adjustable Height Wheeled Frame 88-98cm	5052893000150
RM563095	Compact Adjustable Height Wheeled Frame 95-105cm	5052893000167
RM563373	Domestic Adjustable Height Wheeled Frame 72-81cm	5052893000174
RM563380	Domestic Adjustable Height Wheeled Frame 80-90cm	5052893000181
RM563380/RED	Domestic Adjustable Height Wheeled Frame 80 -90cm RED	5052893001805
RM563388	Domestic Adjustable Height Wheeled Frame 88-97cm	5052893000204
RM563388/RED	Domestic Adjustable Height Wheeled Frame 88 -98cm RED	5052893001812
RM563573	Slimline Adjustable Height Wheeled Frame 73-83cm	5052893000211
RM563580	Slimline Adjustable Height Wheeled Frame 80-90cm	5052893000228
RM563588	Slimline Adjustable Height Wheeled Frame 88-98cm	5052893000235
RM564067	Hospital Adjustable Height Wheeled Frame 67-74cm	5052893000242
RM564077	Hospital Adjustable Height Wheeled Frame 77-84cm	5052893000259
RM564087	Hospital Adjustable Height Wheeled Frame 87-94cm	5052893000266
RM574583	Trough Frame Adjustable Height 83-93cm	5052893000273
RM574583/RED	Trough Frame Adjustable Height 83-93cm RED	5052893002116
RM574598	Trough Frame Adjustable Height 98-108cm	5052893000280
RM574598/RED	Trough Frame Adjustable Height 98-108cm RED	5052893002123
RM585073	Trough Frame Adjustable Height Wheeled 73-83cm	5052893000297
RM585073/RED	Trough Frame Adjustable Height Wheeled 73-83cm RED	5052890002130
RM585083	Trough Frame Adjustable Height Wheeled 83-93cm	5052893000303
RM585083/RED	Trough Frame Adjustable Height Wheeled 83-93cm RED	5052893002147
RM585098	Trough Frame Adjustable Height Wheeled 98-108cm	5052893000310
RM585098/RED	Trough Frame Adjustable Height Wheeled 98-108cm RED	5052893002154
RM587100	Single Trough Frame (83cm - 93cm)	5052893002161



Code	Description	UDI
RM587200	Single Trough Frame (93cm - 103cm)	5052893002178
RM587300	Single Trough Frame (108cm - 118cm)	5052893002185
RM597579	Heavy Duty Adjustable Height Frame 79-89cm 35st MX/USER	5052893000358
RM597587	Heavy Duty Adjustable Height Frame 87-97cm 35st MX/USER	5052893000365
RM598580	Heavy Duty Adjustable Height Wheeled Frame 80-90cm 35st MX/USER	5052893000372
RM598588	Heavy Duty Adjustable Height Wheeled Frame 88-98cm 35st MX/USER	5052893000389