

EU DECLARATION OF CONFORMITY



We,
Drive DeVilbiss Healthcare Ltd,
Sidhil Business Park,
Holmfild,
Halifax,
West Yorkshire,
HX2 9TN,
UK

Hereby declare under our sole responsibility that the devices specified are in conformity with:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

General product name: Wheeled walking frame range

Product variants:

- 10281W-30 Ultra Narrow Wheeled Walking Frame (Medium)
- 10282W-30 Ultra Narrow Wheeled Walking Frame (Large)
- 10283W-30 Wheeled Domestic Walking Frame (Small)
- 10284W-30 Wheeled Domestic Walking Frame (Medium)
- 10285W-30 Wheeled Domestic Walking Frame (Large)
- 10284WFP-30 Wheeled Domestic Walking Frame (Medium) with Forearm Platforms

GMDN code: 31119

BASIC UDI-DI: 50557857WFR002NS

Intended purpose: A walking device manipulated with both arms to assist a person to maintain stability and balance whilst walking.

Risk class: Medical device class I as defined by rule 1 of Annex VIII of EU 2017/745.

Conformity assessment procedure: Issuing of the declaration of conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of regulation EU 2017/745

The medical devices to which this declaration relates comply with the following standards:

EN ISO 11199-1:2021	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 1: Walking frames
EN ISO 11199-2:2021	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators
EN ISO 11199-3:2005	Walking aids manipulated by both arms – Requirements and test methods – Part 3: Walking tables
EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
BS EN 1021-1:2014	Furniture. Assessment of the ignitability of upholstered furniture - Ignition source smouldering cigarette
BS EN 1021-2:2014	Furniture. Assessment of the ignitability of upholstered furniture - Ignition source match flame equivalent
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices.
PD ISO/TR 24971:2013	Medical devices – Guidance on the application of ISO 14971
EN ISO 15223-1:2016	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

Signed for and on behalf of Drive DeVilbiss Healthcare Ltd.

Name: Mr Alastair Fry

Title: Head of international regulatory affairs and compliance

Date of Issue: 4th October 2021

Place of Issue: Drive DeVilbiss Healthcare Ltd, Halifax, HX2 9TN, UK