EC DECLARATION OF CONFORMITY



EC REP

NRS Healthcare, Blaris Industrial Estate 4C Altona Road, Lisburn, Northern Ireland BT27 5QB

(SRN: XI-AR-000031974)



NRS Healthcare, Sherwood House, Cartwright Way, Forest Business Park, Bardon Hill, Coalville, Leicestershire LE67 1UB, UK

(SRN: GB-MF-000034983)

Declare, upon our sole responsibility, that our product;

Item Number (UDI-DI/GTIN): S20768 (5038948207682)

Basic UDI-DI: 5038948AAARZP Item name: HD 4 Wheel Alum. Rollator



Being a Class I Medical Device (GMDN code: 31119)

Complies with the appropriate requirements of EC Council Directives:Regulation 2017/745 – Medical Devices
Directive 93/42/EEC as amended by Directive 2007/47/EEC – Medical Devices
Regulation 1907/2006 (& amendments) – Registration, Evaluation, Restriction & Authorisation of Chemicals

The product complies with the appropriate requirements of the listed harmonised or national standards:

BS EN ISO 11199-2:2005 Walking aids manipulated by both arms – requirements and test methods: Part 2 Rollators.

Intended Use:

The Heavy Duty Rollator is designed to provide support and assistance to those unable to, or who lack the confidence to, walk without some level of support.

lan Smith

Jan Snott

Quality & Compliance Manager Date: July 2023

CERK

Issue 3 PCQA008