





EU DECLARATION OF CONFORMITY

MANUFACTURER		
Name of Company and Address	EUDAMED SRN / Application ID	
 www.ferno.com.au	FERNO Australia Pty Ltd 11 Johnstone Road, Brendale Queensland, 4500 Australia +61 7 3881 4999	AU-MF-000035726 / APP000052128
EU AUTHORIZED REPRESENTATIVE AND IMPORTER		
Name of Company and Address	EUDAMED SRN / Application ID	
 www.ferno.it	FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028	IT-MF-000031330 / APP000027477
UK RESPONSIBLE PERSON AND IMPORTER		
Name of Company and Address	MHRA Reference Number	
 www.ferno.co.uk	FERNO (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999	1270

The manufacturer declares under its own responsibility that the medical device(s):

PRODUCT IDENTIFICATION			
Product Brand Name	Photo		
Ferno Walk Belt			
EMDN			
V0805038002 NON-RIGID SUPPORTS FOR LIFTS (HARNESSES)			
NATO NUMBER (NSN)			
-			
Intended Purpose	A mobility aid used by carers or nurses to assist a disabled or infirm user in walking by providing a means of support.		
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
FWE-WB-LS	Walk Belt with Leg Straps	09348498000302	93484980WBJN
FWE-WB-LS L	Walk Belt with Leg Straps Large	09348498002382	93484980WBJN
RISK CLASS FOR MEDICAL DEVICES			
Device Classification	Common Specifications		
Class I Rule 1	Not applicable		

according to:

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HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	Description
EN ISO 9001:2015	Quality management systems - Requirements (ISO 9001:2015)

complies with the essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.

A handwritten signature in black ink, appearing to read 'Robert Hall'.

Robert Hall
National Quality and Compliance Manager
Perth, Australia
29/05/2023

This document is compiled in accordance with Annex IV - EU declaration of conformity