

EC Declaration of Conformity

to medical device regulation 2017/745

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This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER AN	ID EU RESPONSIBLE PERSON			
Name of Company and Address			EUDAMED SRN	
www.medirol.cz	MEDIROL s.r.o. Na Strži 126/4 140 00 Praha 4 Czech Republic +420 515 338 524	CE	CZ-MF-000006450	
UK RESPONSIBLE PERSON AND IMPORTER				
Name of Company and Address			MHRA Reference Number	
UK REP www.ferno.co.uk	FERNO (UK) Ltd, Ferno House, Stubs Beck Lane Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999	UK	12246	

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

PRODUCT IDENTIFICATION				
Product Brand Name		Photo		
VIPER LOADING SYSTE	M F401			
EMDN				
V08050199				
PATIENT TRANSFER ST	RETCHERS - OTHER			
Intended Purpose				
	em is intended for use by fully qualified, trained and	The state of the s		
competent carers, atte	ndants, paramedics or other such medical staff as an aid			
to assist with loading a	nd unloading of compatible ambulance stretcher to and			
from an ambulance an	d to secure the stretcher during transport.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)	
F401V02	VIPER LOADING SYSTEM F401	08594207730522	859420773VIPERF40127	
RISK CLASS FOR MEDICAL DEVICES				
Device Classification	Common Specifications			
Class I Rule 1	Not applicable	<u> </u>		

according to:

HARMONIZED AND NON-HARMONIZED STANDARDS			
Item	Description		
Annex 1 of EC Regulation 2017/745	General Safety and Performance Requirements.		
EN 1865-5	Patient handling equipment used in road ambulances - Part 5: Stretcher support		
EN 1789	Medical vehicles and their equipment - Road ambulances		

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

Signature
Ing. David Ryska – Chief Executive Officer
Prague, July 8th 2024