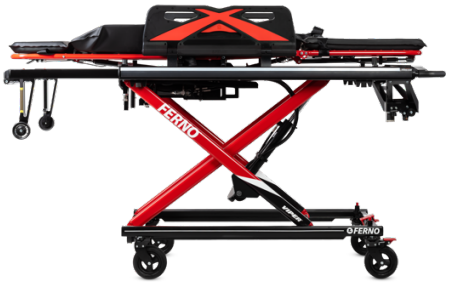
MEDIROL	EC Declaration of Conformity to medical device regulation 2017/745	Doc. Number: Revision Number: A Page: 1 of 2

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

MANUFACTURER AND 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	**CZ-MF-000006450**
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	12246

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

PRODUCT IDENTIFICATION	
Product Brand Name	**Photo**
VIPER M301	
EMDN	
V08050101 GENERIC USE STRETCHERS	
Intended Purpose	
The Viper Stretcher is intended for use by fully qualified, trained and competent carers, attendants, paramedics or other such medical staff as an aid to provide safe and secure transportation of patients. The Viper Stretchers primary intended use is for the transportation of patients, either physically impaired, ill or with other types of injuries from ground or hospital bed level to the ambulance.	

REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
M301V201M01	VIPER M301, SX COTSIDES	08594207730645	859420773VIPERM3013K
M301V201M02	VIPER M301, SX COTSIDES, FOOTBAR	08594207730164	859420773VIPERM3013K
M301V201M03	VIPER M301, NO SIDE ARMS	08594207730652	859420773VIPERM3013K
M301V201M04	VIPER M301, SX, TILD-HEAD BACKREST	08594207730669	859420773VIPERM3013K
M301V201M05	VIPER M301, SX, TILD-HEAD BACKREST, FOOTBAR	08594207730676	859420773VIPERM3013K
M301V201M06	VIPER M301, SX, EXTENDING BACKREST, FOOTBAR	08594207730683	859420773VIPERM3013K
M301V201M07	VIPER M301, SX, EXTENDING BACKREST	08594207730690	859420773VIPERM3013K
M301V201M08	VIPER M301, FOLD-DOWN SIDE ARMS	08594207730706	859420773VIPERM3013K

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class I Rule 1	Not applicable

according to:

HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	**Description**
Annex 1 of EC Regulation 2017/745	General Safety and Performance Requirements.
EN 1865-2	Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
EN 1865-3	Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher
EN 1789	Medical vehicles and their equipment - Road ambulances
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60529	Degrees of protection provided by enclosures (IP Code)
EHK OSN 10/06	Regulation No 46 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of devices for indirect vision and of motor vehicles with regard to the installation of these devices
MHRA	Registered with the UK Competent Authority and additional designated standards referenced to compile the technical documentation detailed in the 'Technical File' as held by the Engineering and Design Manager at the above address.

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