







EU/UK DECLARATION OF CONFORMITY

| MANUFACTURER | |
|--|---|
| Name of Company and Address | EUDAMED SRN / Application ID |
|  FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  www.ferno.it | IT-MF-000031330 / APP000027477 |
| SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER | |
| Name of Company and Address | Swiss Single Registration Number (CHRN) |
|   FERNO S.r.l Pieve di Cento, succursale di Savosa Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00 www.ferno-schweiz.ch | CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER |
| UK RESPONSIBLE PERSON AND IMPORTER | |
| Name of Company and Address | MHRA Reference Number |
|  FERNO (UK) Ltd, Ferno House, Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ +44 (0) 1274 851999 www.ferno.co.uk | 12246 |

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

| PRODUCT IDENTIFICATION | | | |
|---|--|--|-----------------------|
| Product Brand Name | | Photo | |
| FERNO, ScoopEXL stretcher | |  | |
| EMDN | | | |
| V08050103 - EMERGENCY AND TRAUMATOLOGY STRETCHERS | | | |
| Intended Purpose | | | |
| The atraumatic ScoopEXL stretcher is a device made for the aid, immobilization and transport of the patient | | | |
| REF (Item / Catalog) | Item Description | GTIN (UDI-DI) | GMN (Basic UDI-DI) |
| 0108002-R | ScoopEXL yellow, with pin, no restraints, red | 08051380870020 | 805138087V08050103PFA |
| 0107956 | ScoopEXL yellow, no pin, no restraints | 08051380870105 | 805138087V08050103PFA |
| 0108002 | ScoopEXL yellow, with pin | 08051380870112 | 805138087V08050103PFA |
| 0108003 | ScoopEXL yellow, with pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles | 08051380870129 | 805138087V08050103PFA |
| 0108004IT/773 | ScoopEXL yellow, with pin, n. 4 restraints mod. 436l metal buckle | 08051380870143 | 805138087V08050103PFA |
| 0107956-UK | ScoopEXL yellow, no pin, max extension label | 08051380870150 | 805138087V08050103PFA |
| 0107957 | ScoopEXL yellow, no pin, n.3 restraints 2pcs, black with red FERNO logo, metal buckles | 08051380870167 | 805138087V08050103PFA |
| 0107958 | ScoopEXL yellow, no pin, n.3 restraints 1pcs, black with red FERNO logo, metal buckles | 08051380870174 | 805138087V08050103PFA |

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| 0107959-UK | ScoopEXL yellow, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles - max extension label | 08051380870181 | 805138087V08050103PFA |
| 0108039 | ScoopEXL red, no pin | 08051380870211 | 805138087V08050103PFA |
| 0108011 | ScoopEXL red, no pin, n.3 restraints 1pcs, black with red FERNO logo, metal buckles | 08051380870228 | 805138087V08050103PFA |
| 0108012 | ScoopEXL red, with pin, n. 3 restraints mod. 436l plastic buckle | 08051380870235 | 805138087V08050103PFA |
| 0107996 | ScoopEXL grey, no pin | 08051380870242 | 805138087V08050103PFA |
| 0107965 | ScoopEXL grey, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles | 08051380870259 | 805138087V08050103PFA |
| 0108008 | ScoopEXL green, with pin | 08051380870266 | 805138087V08050103PFA |
| 0108000 | ScoopEXL green, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles | 08051380870297 | 805138087V08050103PFA |
| 0107959 | ScoopEXL yellow, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles | 08051380870303 | 805138087V08050103PFA |
| 0107956-BLK | ScoopEXL black, no pin, no restraints | 08051380870877 | 805138087V08050103PFA |
| 0107956-SE | ScoopEXL special edition, no pin | 08051380870884 | 805138087V08050103PFA |
| 0107958-BLK | ScoopEXL black, no pin, n.3 restraints 430-1-N | 08051380870891 | 805138087V08050103PFA |
| 0108001 | ScoopEXL green, no pin, n.3 restraints 430-PA-1-N | 08051380870907 | 805138087V08050103PFA |
| 0108002 | ScoopEXL yellow, with pin, no restraints | 08051380870112 | 805138087V08050103PFA |
| 0108002-BLK | ScoopEXL black, with pin, no restraints | 08051380870914 | 805138087V08050103PFA |
| 0108002-BLKIT | ScoopEXL black, with pin, no restraints, ITA | 08051380870921 | 805138087V08050103PFA |
| 0108002-IT | ScoopEXL yellow, with pin, no restraints, ITA | 08051380870938 | 805138087V08050103PFA |
| 0108002-SE | ScoopEXL special edition, with pin | 08051380870945 | 805138087V08050103PFA |
| 0108004 | ScoopEXL yellow, with pin, n. 3 restraints mod. 436l metal buckle | 08051380870136 | 805138087V08050103PFA |
| 0108004BLK/773-IT | ScoopEXL black, with pin, n.4 restraints metal karabiner, ITA | 08051380870952 | 805138087V08050103PFA |
| 0108004IT/773-IT | ScoopEXL yellow, with pin, n.4 restraints metal karabiner, ITA | 08051380870969 | 805138087V08050103PFA |
| 0108004PIT | ScoopEXL yellow, with pin | 08051380870976 | 805138087V08050103PFA |
| 0108008-IT | ScoopEXL green, with pin, no restraints, ITA | 08051380870983 | 805138087V08050103PFA |
| 0108008IT/773 | ScoopEXL green, with pin, n.4 restraints metal karabiner | 08051380870990 | 805138087V08050103PFA |
| 0108010 | ScoopEXL green, with pin, n.3 restraints plastic karabiner | 08051380871003 | 805138087V08050103PFA |
| 0108033 | ScoopEXL yellow, with pin, n.3 restraints plastic karabiner | 08051380871010 | 805138087V08050103PFA |
| 0108038 | ScoopEXL red, with pin | 08051380870198 | 805138087V08050103PFA |
| 0108038-IT | ScoopEXL red, with pin, no restraints, ITA | 08051380871652 | 805138087V08050103PFA |
| 0108038IT/773 | ScoopEXL red, with pin, n.4 restraints metal karabiner | 08051380871027 | 805138087V08050103PFA |
| 21-00044 | ScoopEXL yellow, with pin, n.4 restraints 430-PA-2-N | 08051380871034 | 805138087V08050103PFA |
| 21-00046 | ScoopEXL green, no pin, n.3 restraints 430-1-N | 08051380871041 | 805138087V08050103PFA |
| KIT-SCOOPEXL | ScoopEXL complete, yellow | 08051380871232 | 805138087V08050103PFA |
| 21-00026 | Emergency Kit with ScoopEXL yellow and B-LOCK | 08051380871270 | 805138087V08050103PFA |
| 21-00038 | ScoopEXL complete, red | 08051380871287 | 805138087V08050103PFA |
| 21-00039 | ScoopEXL complete, black | 08051380871478 | 805138087V08050103PFA |

| Device Classification | Common Specifications |
|-----------------------|-----------------------|
| Class I Rule 1 | Not applicable |

according to:

| HARMONIZED AND NON-HARMONIZED STANDARDS | |
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| Item | Description |
| EN 1865-1:2010+A1:2015 | Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment. |
| EN ISO 10993-1:2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018) |
| EN ISO 14971:2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN 62366-1:2015 | Medical devices - Part 1: Application of usability engineering to medical devices |
| EN ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN ISO 13485:2016+A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| 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 and with the Medical Devices Regulation 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791), 2020 (SI 1478) and 2023 (SI 627).

Pieve di Cento, February 19, 2024

Signature

Enrico Carletti - Managing Director, PRRC

