



**EU DECLARATION OF CONFORMITY**

MANUFACTURER		
Name of Company	Address	SRN / Application ID
FERNO S.r.l	Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy	Not yet available / APP000027477

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

PRODUCT IDENTIFICATION			
Product Brand Name		Photo	
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)
00108002-R	ScoopEXL yellow, with pin, no restraints, red	08051380870020	805138087V08050103PFA
0107956	ScoopEXL yellow, no pin, no restraints	08051380870105	805138087V08050103PFA
0108002	ScoopEXL yellow, (pin)	08051380870112	805138087V08050103PFA
0108003	ScoopEXL yellow, pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles	08051380870129	805138087V08050103PFA
0108004	ScoopEXL yellow, with pin, n. 3 restraints mod. 436l metal buckle	08051380870136	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
0107959-UK	ScoopEXL yellow, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles - max extension label	08051380870181	805138087V08050103PFA
0108038	ScoopEXL red (pin)	08051380870198	805138087V08050103PFA
0108038ITNO773	ScoopEXL red, with pin, n. 4 restraints mod. 436l metal buckle	08051380870204	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 (pin)	08051380870266	805138087V08050103PFA
0108008NO773	ScoopEXL green, pin, n.3 restraints mod 436l, metal buckle	08051380870273	805138087V08050103PFA
0107999	ScoopEXL green (no pin)	08051380870280	805138087V08050103PFA
0108000	ScoopEXL green, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles	08051380870297	805138087V08050103PFA
107959	ScoopEXL yellow, no pin, n.3 restraints 2pcs, black with red FERNO logo, plastic buckles	08051380870303	805138087V08050103PFA

**RISK CLASS FOR MEDICAL DEVICES**

Device Classification	Common Specifications
Class I Rule 1	Not applicable

according to:

**HARMONIZED AND NON-HARMONIZED STANDARDS**

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 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.

Pieve di Cento, March 31<sup>th</sup> 2021

Signature

Enrico Carletti - Managing Director