






EU DECLARATION OF CONFORMITY

MANUFACTURER	
Name of Company and Address  FERNO S.r.l Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028  www.ferno.it	EUDAMED SRN / Application ID IT-MF-000031330 / APP000027477
SWISS AUTHORIZED REPRESENTATIVE AND IMPORTER	
Name of Company and Address   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	Swiss Single Registration Number (CHRN) CHRN-AR-20002332 - AUTHORIZED REPRESENTATIVE CHRN-IM-20002288 - IMPORTER

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

PRODUCT IDENTIFICATION			
Product Brand Name		Photo	
FERNO, SLAM Stretcher locking system			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
The SLAM device is an accessory used to secure a transportable Ferno stretcher in the road ambulance without the use of tools. The SLAM is available in various models in order to fit several stretchers and loading systems.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
SLAM-26	SLAM locking system for stretchers 26-S and 26-B	08051380870556	805138087V0880SLAMLS
SLAM-26+	SLAM locking system for stretcher 26-S (with update)	08051380870563	805138087V0880SLAMLS
SLAM-26/PAS	SLAM locking system for stretcher 26-S for PAS plan	08051380870570	805138087V0880SLAMLS
SLAM-26/PAS+	SLAM locking system for stretcher 26-S for PAS plan (with update)	08051380870587	805138087V0880SLAMLS
SLAM-26B/PAS	SLAM locking system for stretcher 26-B for PAS plan	08051380870594	805138087V0880SLAMLS
SLAM-5026/EFX	SLAM locking system for stretchers 5026, EFX, CUSTOM-M	08051380870600	805138087V0880SLAMLS
SLAM-4050	SLAM locking system for stretchers 4051 and 4052	08051380870617	805138087V0880SLAMLS
SLAM-4050/PAS	SLAM locking system for stretchers 4051 and 4052 for PAS plan	08051380870679	805138087V0880SLAMLS
SLAM-5026/MONDIAL	SLAM locking system for stretchers 5026 and MONDIAL	08051380870662	805138087V0880SLAMLS
SLAM-5026/PAS	SLAM locking system for stretchers 5126 and 5226 for PAS plan	08051380870686	805138087V0880SLAMLS
SLAM-28	SLAM locking system for stretchers 28	08051380870693	805138087V0880SLAMLS
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 1789:2020 para(s). 4.4.11 and 5.3	Medical vehicles and their equipment - Road ambulances
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
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.

Pieve di Cento, April 20, 2023

Signature

Enrico Carletti - Managing Director, PRRC

