

EU 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

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

PRODUCT IDENTIFICATION			
Product Brand Name	Photo		
FERNO, 561 FASTENER FOR SCOPEXL			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
Designed especially for fastening the SCOPEXL stretcher inside the ambulance in vertical or horizontal position.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
561-V	VERTICAL FASTENER FOR SCOPEXL	08051380871225	805138087V08805613Q
561-O	HORIZONTAL FASTENER FOR SCOPEXL	08051380871423	805138087V08805613Q
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 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, January 03, 2024

Signature

Enrico Carletti - Managing Director, PRRC

