


**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	
TSL Expander			
EMDN			
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES			
Intended Purpose			
TSL Expander is an accessory to the ScoopEXL stretcher for the movement and transport of large sized patients.			
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
25-0030-002	TSL Expander for ScoopEXL 1 piece	08051380870310	805138087V0880TSLCN
25-0030-003	TSL Expander for ScoopEXL (MANU00090)	08051380870327	805138087V0880TSLCN

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

tested for:

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, May 26th 2021

Signature

Enrico Carletti - Managing Director

