FERNO

FERNO S.R.L. *n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale*

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EU DECLARATION OF CONFORMITY
Regulation (EU) 2017/745

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**	
STBC			
EMDN			
V08050103 - bio-containment stretchers			
Intended Purpose			
Bio-containment system for ambulance transport is intended to be used together with Ferno stretchers. It allows the isolation of the patient with suspected contagious disease from the surrounding areas, considerably reducing the risk of transmission.			
REF (Item / Catalog)	**Item Description**	**GTIN (UDI-DI)**	**GMN (Basic UDI-DI)**
21-00008	Bio-containment system for ambulance transport	08051380870013	805138087V08050103STBCT7

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class I Rule 13	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 1789:2020 para(s). 4.4.11 and 5.3	Medical vehicles and their equipment - Road ambulances
EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1:2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
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 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, LVD Directive 2014/35/EU, EMC Directive 2014/30/EU and do not contain any of the restricted substances referred to in Annex VI in the RoHS Directive 2011/65/EU & Directive (EU) 2015/863.

Pieve di Cento, March 10th 2022

Signature
Enrico Carletti - Managing Director

This document is compiled in accordance with *Annex IV - EU declaration of conformity*

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