

FERNO S.R.L.

VAT NUMBER 01693660977 Capital € 53.712,00 Sole shareholder

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EU DECLARATION OF CONFORMITY

MANUFACTURER			
Name of Company and Address		EUDAMED SRN / Application ID	
www.ferno.it	FERNO S.r.I Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy +39 (051) 6860028	IT-MF-000031330 / APP000027477	
SWISS AUTHORIZED REPR	ESENTATIVE AND IMPORTER		
Name of Company and Address		Swiss Single Registration Number (CHRN)	
CH REP www.ferno-schweiz.ch	FERNO S.r.I Pieve di Cento, succursale di Savosa Via Tesserete, 67 6942 Savosa, Switzerland +41 (41) 259 60 00	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, EARS				
EMDN		O FERRIDO VILLO VILLO		
V0880 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES				
Intended Purpose				
Anti-rotation sail for basket stretcher is an accessory intended to be				
used together with basket type Ferno stretchers to guarantee correct				
rotation management during patient recovery.				
REF (Item / Catalog)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)	
EARS	Anti-rotation sail for basket stretcher	08051380870006	805138087ACCEXMZCEARSME	
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 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 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, March 9, 2023

Signature Enrico Carletti - Managing Director, PRRC Mics 0

FORM-021-02 2022-12-15 EN

Company subject to management and coordination pursuant to article 2497 bis of the italian civil code by Ferno inc. - 70 Weil Way - Wilmington, Ohio 45177

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

EC REP EUROPEAN AUTHORIZED REPRESENTATIVE

