

## **Declaration of Conformity**

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Traverse Rescue LLC	2715 Bristol Circle, Unit 2 Oakville, Ontario, Canada L6H 6X5	CA-MF-000037070

EU AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/Email
Ferno S.r.l.	via B.Zallone, n.26,40066	IT-AR-000031265	+39.051.6860028
CE	Pieve di Cento, Bologna, Italy		www.ferno.it

UKCA REPRESENTATIVE			
Name of Company	Address	SRN	Telephone
Ferno (UK) Limited	Ferno House	TBD	+44 (0) 1274 851999
UK	Stubs Beck Lane,		www.ferno.co.uk
CÀ	Cleckheaton,		
<b>_</b> _	West Yorkshire,		
	BD19 4TZ		
	United Kingdom		

PRODUCT IDENTIFICATION	
Product Brand Name	Photo
Gazelle Series Rescue Litter	
EMDN	
V08050101 -Generic Use Stretcher	
Intended Purpose Gazelle Series Rescue Litters are for professional use and re intended to be used as Rescue Hand Carried Litter.	



P 866.998.7866 F 905.615.1367 E info@traverserescue.com W traverserescue.com 2715 Bristol Circle Oakville, ON L6H 6X5 Canada

Item / Catalog #	Item Description	GTIN UDI	Basic UDI-DI
11-0105	Gazelle Rescue Litter, Regular	00831566000155	83156600V08050101GSC5
11-0106	Gazelle Rescue Litter, Tapered	00831566000162	83156600V08050101GSC5
11-0107	Gazelle Rescue Litter, Confined	00831566000179	83156600V08050101GSC5
	Space		
11-0105B	Gazelle Rescue Litter, Regular	00831566001107	83156600V08050101GSC5
11-0106B	Gazelle Rescue Litter, Tapered	00831566001114	83156600V08050101GSC5
11-0107B	Gazelle Rescue Litter, Confined	00831566001121	83156600V08050101GSC5
	Space		

RISK CLASS FOR MEDICAL DEVICES	
<b>Device Classification</b>	Common Specifications
Class I Self Certified	Not applicable
Rule 1	

Traverse Rescue LLC, declares that the above-mentioned products meet the provision of the following legislation:

- (EU) 2017/745 Medical Device Regulation (effective 5/26/2021)
- List other legislation/Directives as applicable:
  - o MDD 93/42/EEC
  - o EN ISO 9001:2015

**COMPANY REPRESENTATIVE: Sophia Hatsisavvas** 

TITLE: Director of Regulatory SIGNATURE: \_\_\_\_ SIGNATURE: \_\_\_\_

PLACE: Oakville, Ontario, Canada DATE: June 15, 2023