Declaration of Conformity

for the Xtract™SR

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed. This EU Declaration of conformity is issued under the sole responsibility of the manufacturer. Annex 4 MDR DOC EU MDR 2017/745

General Product Name:	Xtract™SR
GMDN Code	13818
Legal Manufacturer: (Name on Label)	**TSG Associates LLP** Albany Works, Long Lover Lane, Pellon, Halifax, Hx14QF United Kingdom.
Manufacturers SRN:	UK-MF-000036201
Variants:	Xtract™SR V4R Xtract™SR V4S
Intended Purpose:	The Xtract™SR is a rescue litter designed for operators to quickly move the combat casualty.
MDR Classification:	Class I Rule 1 Non- Invasive Device
Notified Body:	Not Applicable
EC Certificate:	Not Applicable as Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing the Declaration of Conformity in accordance with Article 19 after the technical documentation as laid out in Annexes II and III have been drawn up

Name Colin Smart **Position** Partner

Signed  **Date** 12.10.23 **Place** TSG Associates United Kingdom

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
Permanent Deformation of lying test	Test the performance in accordance to permanent deformation of the lying test test method 5.4.1 BS EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances. General stretcher systems and patient handling equipment.
Non Ignition Test	The 'Xtract™SR Stretcher' has achieved a classification of 'non-ignition' when tested to EN 597-1:2015 assessment of the ignitability of mattresses and upholstered bed bases: ignition source: smouldering cigarette.
Wash Test	Test the performance of the Xtract™SR in accordance to Domestic washing and drying procedures for textile test method EN 6330:2012 Textiles.

Appendix II – Product Listing / Schedule

Catalogue Number / UDI-DI	Device Name	Basic UDI-DI	EMDN Code
5060766500096	Xtract™SR V4S	5060766500096W9	V08050199
5060766500072	Xtract™SR V4R	5060766500072VT	V08050199

Version History

Version	Compiled by	Date	Description
1		22.03.22	Included the Basic UDI-DI
2		23.03.23	Added the XtractSR V4S and XtractSR V4R
3		12.10.23	To include the wording sole responsibility of the manufacturer