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 covered by this EU Declaration of Conformity is in conformity with Regulation 2017/745. This EU Declaration of conformity is issued under the sole responsibility of the legal manufacturer.

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
Intended Purpose:	The Xtract™SR is a patient rescue stretcher designed for operators to quickly move the combat casualty.
MDR Classification:	Class I Rule 1
Basic UDI - DI	506076650SRSX
EMDN Code	V08050199
Notified Body:	Not applicable. Class I; non-measuring, non-sterile
EC Certificate:	Not applicable. Class I; non-measuring, non-sterile
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 and Annexes I, II, III, IV, VIII of the Medical Devices Regulation 2017/745

Name: Colin Smart **Position:** Partner **Date:** 12.11.2024

Signed: **Place:** TSG Associates, Halifax, England HX1 4QF

TSG Associates is the legal manufacturer, and this EU Declaration of Conformity is issued under the sole responsibility of TSG Associates.

Appendix I – Applicable Standards and Regulation

This present declaration is also in conformity with the following European Regulation, 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 ISO 15223-1:2021	Medical Devices – Symbols to be used with information to be supplied by the manufacturer
EN ISO 14971:2019/A11:2021	Medical Devices – Application of Risk Management to Medical Devices
BS EN 1865-1:2010+A1:2015 Permanent Deformation of lying test	Test the performance in accordance to permanent deformation of the lying 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.
EN ISO 13485:2016/A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN 597-1:2015 Non-Ignition Test	The 'Xtract™SR Stretcher' has achieved a classification of 'non-ignition' when tested to assessment of the ignitability of mattresses and upholstered bed bases: ignition source: smouldering cigarette.
EN 6330:2012 Wash Test	Test the performance of the Xtract™SR in accordance to Domestic washing and drying procedures for textile test method Textiles.

Appendix II – Product Listing / Schedule

Device Name	Catalogue Number	Basic UDI-DI	EMDN Code
Xtract™SR V4S	5060766500096	506076650SRSX	V08050199
Xtract™SR V4R	5060776650072	5060766500072VT	V08050199