

Declaration of Conformity

for the Xtract™SR

TSG declares the above named device complies with the UK medical Devices Regulations 2002 (SI 2002 No 618 as amended) which were amended by the medical devices (Amendment etc) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020

The undersigned declares that the products described in this document meet the regulatory provisions that apply to them and the UKCA Mark may be affixed.

General Product Name:	Xtract™SR
GMDN Code	13818
Legal Manufacturer: (Name on Label)	<u>TSG Associates LLP</u> Albany Works, Long Lover Lane, Pellon, Halifax, HX1 4QF United Kingdom.
Manufacturers SRN:	UK-MF-000036201
Risk Class of Product	1
Annex Used in the Conformity Assessment	Annex VII
Intended Purpose:	The Xtract™SR is a rescue litter designed for operators to quickly move the combat casualty.
Declaration of	Placed on the market under the sole responsibility of the manufacturer.
EU Authorised Representative	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234

Name Colin Smart **Position** Partner

Signed  **Date** 06.06.24 **Place** UK

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

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.

