Declaration of Conformity

for the Xtract™SR Afloat

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 Afloat GMDN 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:	N/A No Variants.
Intended Purpose:	The Xtract™SR Afloat is a non-sterile, reusable flotation device which works in conjunction with the Xtract™SR to cross a water obstacle in challenging environments.
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 UK

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
Buoyancy Testing	Test the performance of the Xtract™SR Afloat to a buoyancy test method in accordance to BS EN ISO 12402-9:2006+A1:2011 Personal flotation devices

Appendix II – Product Listing / Schedule

Catalogue Number / UDI-DI	Device Name	Basic UDI-DI	EMDN Code
5060766500102	Xtract™SR Afloat V2	506076650F2PS	V0880

Version History

Version	Compiled by	Date	Description
1		22.03.22	Included the Basic UDI-DI.
2		28.03.23	V2 sample and amended UDI-DI
3		29.06.23	Including the SRN
4		12.10.23	To include the wording sole responsibility of the manufacturer