

Declaration of Conformity

The undersigned declare that the devices named in this document meet the applicable provisions of the Regulation (EU) 2017/746, UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR) and all applied standards.

Name of the Product(s):	T-Store® Tissue Storage and Transportation Medium CellShip Cell Transport Medium
Product codes:	See specification (Appendix 1)
Legal Manufacturer:	Life Science Group Ltd., The Science Centre, 1, Blaydon Road, Sandy, Bedfordshire, SG19 1RZ, United Kingdom
Intended Use:	For the containment of cell and/or tissue samples for laboratory analysis
IVD Regulation Category:	Class A in accordance with Annex VIII Rule 5 (c)
IVD UK Category:	General IVD
IVD Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the (EU) 2017/746 (IVDR)
UK Assessment Route:	IVD UK MDR 2002 Part IV, Annex III
Applicable Regulations:	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices as amended by Directive 98/79/EC of the European Parliament and of the Council UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR)
Applied Standards:	EN ISO 13485:2016 +A11:2021 EN ISO 14971:2019 EN ISO 15223-1:2021
EU Authorized Representative:	300K Solutions S.L Calle Rio Adaja, 10, 37185, Villamayor, Salamanca, Spain
SRN for EU Authorised Representative:	ES-AR-000040356
GMDN Code:	52735

Date: 07 Jul 2025

Signature:



Location: Sandy, United Kingdom

Jennifer Murray (Managing Director)

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Appendix 1 – Specification

No.	Product Description	Product Code	Size (mL)
1	T-Store® Tissue Storage and Transportation Medium	TSTORE-C	50
2		TSTORE-B	100
3		TSTORE-P	125
4		TSTORE-Y	250
5		TSTORE-A	500
6		TSTORE-L	1000
13	CellShip Cell Transport Medium	SCS-004K	25
14		SCS-004C	50
15		SCS-004B	100