

# MDR & UKCA DECLARATION OF CONFORMITY CRYOGENIC STORAGE AND TRANSPORTATION VESSELS

This Declaration of Conformity is issued under the sole responsibility of IC Biomedical, LLC. The devices covered by the present Declaration is in conformity with all regulations or directives below, including compliance with related General Safety and Performance Requirements.

<b>Manufacturer:</b>	IC Biomedical, LLC 1031 Cass-White Road, Cartersville, Georgia 30121 <b>SRN: US-MF-000024845</b>	<b>EU Authorised Representative:</b>	Medical Product Service GmbH Borngasse 20 35619 Braunfels, Germany <b>SRN: DE-AR-000005009</b>
<b>Swiss Authorised Representative:</b>	Medical Product Service C/O Accumed Sagl Viale Sefontana 7 6834 Morbio Inferiore, Switzerland <b>CHRN: CHRN-AR-20000308</b>	<b>UK Responsible Person:</b>	IC Biomedical UK Ltd Unit 1, Polar Park, Bath Road, Sipson, West Drayton, Middlesex, UB7 0EX United Kingdom

Products and UDI-DI:		
Aluminum Storage and Transportation Vessels Basic UDI-DI: 00850038669140	LABS Series Cryostorage Systems Basic UDI-DI: 00850038669003	K Series Cryostorage Systems Basic UDI-DI: 00850038669065
<b>TW Series – LN2 Freezers</b> TW 35 - 00850038669454 TW 35-10 - 00850038669249 TW 47-6 - 00850038669461 TW 47-10 - 00850038669430  <b>LS Series - Laboratory System Cryogenic Refrigerators</b> LS750 - 00850038669102 LS2000 - 00850038669379 LS3000 - 00850038669386 LS4800 - 00850038669409 LS6000 - 00850038669416  <b>Vapor (Dry) Shippers</b> 4D - 00850038669645 4DX - 00850038669652 10DX - 00850038669669	LABS20K - 00850038669010 LABS40K - 00850038669027 LABS80K - 00850038669034 LABS94K - 00850038669041  Evolution 413 - 00850038669553 Evolution 414 - 00850038669577 Evolution 415 - 00850038669591 Evolution 613 - 00850038669683 Evolution 614 - 00850038669706 Evolution 615 - 00850038669720  Revolution 413 - 00850038669546 Revolution 414 - 00850038669560 Revolution 415 - 00850038669584 Revolution 613 - 00850038669676 Revolution 614 - 00850038669690 Revolution 615 - 00850038669713	3K - 00850038669058 10K - 00850038669072 24K - 00850038669089 38K - 00850038669096
<b>Serial Numbers:</b>	10L24120001 Onwards, 10V24120001 Onwards and 10S24120001 Onwards	

<b>Intended Purpose:</b>	Cryogenic Storage and Transportation Vessels from IC Biomedical are medical devices designed for cryogenic long-term storage and transportation of canisters or vials with biological specimens of human origin, such as cord blood, stem cells or semen for subsequent research or introduction into the human body at extremely low temperatures of between -100°C and -196°C using liquid nitrogen as a cryogenic agent at normal atmospheric pressure.
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<b>Device Classification:</b>	Class IIa – Non-Implantable (MDR Annex VIII, Rule 2)
<b>Start of CE and UKCA Marking:</b>	Effective 18 March 2024
<b>Product Group Codes:</b>	EMDN W020702 - Cryogenics/Frozen

This declaration applies to all CE and UKCA marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn. I, the undersigned, hereby declare the equipment specified above meets the General Safety and Performance Requirements and conforms to the following, as certified by BSI Group The Netherlands B.V. (Netherlands) – NB 2797, and BSI Assurance UK Ltd – NB 0086.

**Medical Device Regulation (MDR) (EU) 2017/745** (Certificate MDR 769446)

**The UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)** (Certificate UKCA 769447)

**EN ISO 13485:2016, Quality Management Systems** (Certificate MD 750919)

  
Signature

David Bowers  
Director Europe Quality and Regulatory  
Name and Title (Print)

21-03-2024  
Date (DD-MM-YYYY)