Declaration of Conformity
MDD, RoHS 3

Legal Manufacturer/ Address	MVE Biological Solutions 3055 Torrington Drive Ball Ground, GA 30107, USA
Manufacturing Facilities	MVE Cryogenic Biological Equipment (Chengdu) Co., Ltd. No. 48 Qingma Rd, South Section Chengdu Modern Industrial Park Pidu District Chengdu 611730 Sichuan Province, China
Notified Body	GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS France
Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunsfel, Germany
Product Families	**YDS series,** YDH **series,** ET **series,** LT **series, A-200, JPN-11-64, XC 38/9, CryoCube** series, BL-7, **CryoShipper** CT Series
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 2)
Global Medical Device Nomenclature (GMDN) Code	16534, 16535
Start of CE Marking	Effective 18 November 2002

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 essential requirements and conforms to the following, as certified by G-MED, NB 0459.

Council Directive 93/42/EEC, Medical Devices Directive and Amendment 2007/47/EC (Certificate 38027)

EN ISO 13485: 2016, Quality Management Systems (Certificate 38025)

These devices also conform to the following Directive(s):

Commission Delegated Directive (EU) 2015/863 (commonly referred to as Restriction of Hazardous Substances – RoHS 3): for all units manufactured on or after 2014-10-15.

Article 120 of Regulation (EU) 2017, Medical Devices Regulation (MDR)

Refer to authenticated product list for models and part numbers.

	Max Mortensen, VP of QA/RA	22 February 2021
Signature	Name and Title (Print)	Certification Date (DD-MM-YYYY)