CAIRE Inc.
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MANUFACTURER'S DECLARATION OF CONFORMITY
AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
FULL QUALITY ASSURANCE PROCEDURE

This is a declaration of conformity made under Clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's Name:	CAIRE Inc.
Business Address:	2200 Airport Industrial Drive, Suite 500, Ball Ground, GA 30107 USA
Medical Device(s):	SAROS 4000
Classification:	IIa
GMDN Code and Terms:	31321 – Portable Oxygen Concentrator
Scope of Application:	This declaration applies to all products to which the full quality assurance procedures applies

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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Full Quality Assurance procedures certificate:	MDD Certificate No. 31275 European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Devices
Standards Applied:	EN ISO 13485:2016 / ISO 13485:2016 ISO 780:2015 EN 1041:2008 EN ISO 15223-1:2016 ISO 80601-2-67:2014 ISO 80601-2-69:2014 EN ISO 10993-1:2009/AC:2010 EN ISO 14971:2012 / ISO 14971:2007 BS EN 55011:2016 + A11:2020 IEC 60068-2-27:2008 BS EN 60529:1992+A2:2013 EN 60601-1:2006/A1:2013 / IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-1-6:2010+A1:2013 IEC 60601-1-8:2006+A1:2012 IEC 60601-1-12:2014 IEC 60812:2018 IEC 62304:2006+A1:2015 IEC 62366-1:2015/COR1:2016 IEC 62366:2007+A1:2014 IEC 80416-1:2008 ISO 7000:2019 ISO 7010:2019/AMD 1:2020

Authorised Signatory:

Nov 15, 2023

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Ted Vlahopoulos – Sr. Regulatory Specialist Date