

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.

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

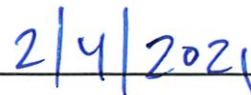
Standards Applied:

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:



Edward Kim, Vice President - Engineering and Regulatory



Date