Declaration of Conformity
MDD, RoHS 2

CE 0459

Legal Manufacturer / Address	CAIRE Inc. 2200 Airport Industrial Drive Suite 500 Ball Ground, GA 30107 USA
Manufacturing	CAIRE Inc. 2205 Airport Industrial Drive Ball Ground, GA 30107 USA
Distribution & order fulfilment, final configuration	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany
Notified Body	GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS France
Authorized Representative	Medical Product Service GmbH (MPS) Borngasse 20 35619 Braunfels, Germany
Product Families	Oxygen Therapy Flowmeter Stand – Model SureFlow
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 2)
Global Medical Device Nomenclature (GMDN) Code	37132 - Oxygen Therapy Flowmeter
Start of CE Marking	3 April 2019

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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 GMED SAS, NB 0459.

- **Council Directive 93/42/EEC, Medical Devices Directive (Annex II, excluding section 4) and Amendment 2007/47/EC** (Certificate 31275)
- **EN ISO 13485:2016, Quality Management Systems** (Certificate 31276)

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

- **Council Directive 2011/65/EU, Restriction of hazardous substances**

Edward Kim, Vice President – Engineering and Regulatory

2/4/2021
Date