

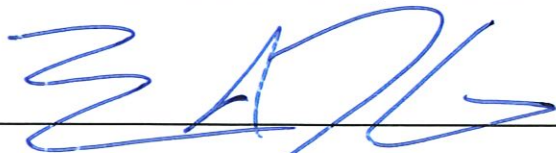
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|---|--|
| <b>Legal Manufacturer / Address</b>                             | CAIRE Inc.<br>2200 Airport Industrial Drive Suite 500<br>Ball Ground, GA 30107 USA   |
| <b>Manufacturing</b>  | CAIRE Inc.<br>2205 Airport Industrial Drive<br>Ball Ground, GA 30107 USA             |
| <b>Distribution &amp; order fulfilment, final configuration</b> | CAIRE Medical Germany GmbH<br>Arnold-Höveler-Strasse 2,<br>40764 Langenfeld, Germany |
| <b>Notified Body</b>  | GMED SAS (0459)<br>1, rue Gaston Boissier<br>75015 PARIS<br>France                   |
| <b>Authorized Representative</b>                                | Medical Product Service GmbH (MPS)<br>Borngasse 20<br>35619 Braunfels, Germany       |
| <b>Product Families</b>   | Oxygen Therapy Flowmeter Stand – Model SureFlow                                      |
| <b>MDD Device Classification</b>                                | Class IIa (MDD Appendix IX, Rule 2)  |
| <b>Global Medical Device Nomenclature (GMDN) Code</b>           | 37132 - Oxygen Therapy Flowmeter   |
| <b>Start of CE Marking</b>                                      | 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This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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