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| Legal Manufacturer / Address | CAIRE Inc. 2200 Airport Industrial Dr, Suite 500 Ball Ground, GA 30107, USA | |
| Manufacturing/Repair Facilities | CAIRE Inc. 2205 Airport Industrial Drive Ball Ground, GA 30107 USA | CAIRE Medical Technology (Chengdu) Co., Ltd. No. 48 Qingma Road, South Section Chengdu Modern Industrial Park Pidu district, Chengdu 611730, Sichuan China |
| Repair Facilities | CAIRE Medical Italy Srl Via 10 Canada 35127 Padova, Italy | |
| Repair, distribution & order fulfilment | CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany | CAIRE Medical Ltd. Unit 6- Ashville Way Wokingham, Berkshire RG41 2PL United Kingdom |
| 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 Concentrators (Eclipse Oxygen System and FreeStyle Comfort) | |
| MDD Device Classification | Class IIa (MDD Appendix IX, Rule 11) | |
| Global Medical Device Nomenclature (GMDN) Code | 31321-Portable Oxygen Concentrator | |
| Start of CE Marking | Eclipse Oxygen System: 14 March 2007 FreeStyle Comfort: 01 March 2018 | |
| Technical File Reference | Eclipse: ECLIPSE-MDD-TF-01 FreeStyle Comfort: FREESTYLE COMFORT-MDD-TF-01 | |
| Effective Date | May 1, 2021 | |
| Expiration Date | May 26, 2024 | |

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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, Article 120 Transitional provisions under MDR (2017/745) (GMED SAS Certificate No° 31275 rev. 14, Expiry Date: May 26, 2024)**
- **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; Directive (EU) 2015/863, amending Annex II to 2011/65/EU**



Edward Kim, Vice President – Engineering and Regulatory