

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	
Repair, distribution & order fulfilment	CAIRE Medical Germany GmbH Arnold-Höveler-Strasse 2, 40764 Langenfeld. Germany	CAIRE Medical Ltd. Unit 6- Ashville Way Wokingham, Berkshire RG412PL United Kingdom
Notified Body	GMED SAS (0459) 1, rue Gaston Boissier 75015 PARIS France	
Authorized Representative	Medical Product Service GmbH (MPS) Bornegasse 20 35619 Braunfels, Germany	
Product Families	Oxygen Concentrators (Saros 4000)	
MDD Device Classification	Class IIa (MDD Appendix IX, Rule 11)	
Global Medical Device Nomenclature (GMDN) Code	31321-Portable Oxygen Concentrator	
Start of CE Marking	Saros 4000: 05 March 2020	
Technical File Reference	SAROS-MDD-TF-02	

This declaration applies to all CE marked devices manufactured from date of issuance until it is either superseded by another declaration or withdrawn.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; Directive (EU) 2015/863, amending Annex II to 2011/65/EU**



Edward Kim, Vice President – Engineering and Regulatory

July 6, 2021

Date