APRAGAZ

Member of CEOC INTERNATIONAL

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BELAC Cert N°084-QMS

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY In accordance with Appendix II (excluding section 4) of the Medical Devices Directive 93/42/EC and its amendment 2007/47/EC		Certificate N° 14/US/3475-1-REV 0 Page 1/2
Manufacturer	Name	**AIRSEP CORPORATION**
	Address	260 Creekside Drive (B1) Buffalo (NY) 14228 USA
Production / Repair Facilities	Name	**AIRSEP CORPORATION**
	Address	500 Commerce Drive (B2) Buffalo (NY) 14228 USA
	Name	**Chart Biomedical (Chengdu) Co. Ltd (CH)**
	Address	No. 48 Qingma Road, South Section Chengdu Modern Industrial Park Pixian Chengdu, 611730, Sichuan (CH) CHINA
Authorized EC Representative	Name	**MPS - MEDICAL PRODUCT SERVICE GmbH**
	Address	Borngasse, 20 35619 Braunfels GERMANY

Scope : Design , manufacturing and inspection of Oxygen concentrators and their components

- Category IIa devices : Stationery Oxygen concentrators (GMDN Code : P12813)
- Category IIa devices : Portable Oxygen concentrators (GMDN Code : P31321)
- Category IIb devices : PSA oxygen generators (GMDN Code : P12813)

Concerned Equipment: See page 2/2

This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EC and its amendment 2007/47/EC and conforms to the requirements for the equipment shown above. The approval is subject to the continued maintenance of the Quality System in accordance with the requirements of the above Directive, this shall be controlled by intermediate audits, inspections and surveys.

The manufacturer is allowed to affix the "CE" mark followed with our notified body identification number 0029 to the above mentioned devices in the conditions described in the Directive.

The approval is valid until 30/11/2019

Date : **01/12/2014** Name/*Nom* : **Ch. Leplat** Position **General Manager**

Notified body identification number : **0029** Signature

Notified body stamp : **APRAGAZ Belgium Inspecting Authority** P.O. B. Neve

Notified body reference : **P16526/011**

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Concerned Equipments

FOCUS *(Portable Oxygen Concentrators)*;	Technical file ref.: F2MF-900 (B2)
FreeStyle *(Portable Oxygen Concentrators)*;	Technical file ref.: FSMF-900 (B2)
FreeStyle 5 *(Portable Oxygen Concentrators)*;	Technical file ref.: F5MF900 (B2)
NewLife Elite *(Oxygen Concentrators)*;	Technical file ref.: NLMF900 (B2)
NewLife Intensity 8 *(Oxygen Concentrators)*;	Technical file ref.: 8LMF900 (B2)
NewLife Intensity 10 *(Oxygen Concentrators)*;	Technical file ref.: 10MF900 (B2)
SureFlow ; *(Flowmeter)*;	Technical file ref.: SFMF900 (B2)
VisionAire 2 & VisionAire 3 *(Oxygen Concentrators)*;	Technical file ref.: V3MF900 (B2)
VisionAire & VisionAire V *(Oxygen Concentrators)*;	Technical file ref.: VAMF900 (B2 + CH)
AS Series *(Oxygen Generators)*;	Technical file ref.: ASMF 900 (B1)

Date : **01/12/2014** Name/*Nom* : **Ch. Leplat** Position **General Manager**

Notified body identification number : **0029** Signature

Notified body stamp : **APRAGAZ Belgium Inspecting Authority** P.O. B. Neve

Notified body reference : **P16526/011**