Certificate – Сертификат – 證明書 – Certificat – 証明書 – شهادة

Certificate of Compliance

No. 08180823.LALTU55

Certificate's Holder:	Linde Arooxy (Xi'an) Life Science Co., Ltd. 4th Floor, Unit 2, Block 10, No.2 National Science & Technology Enterprise Accelerator, No.6 Qinling Road, High-tech District, Xi'an, Shaanxi, China
Certification ECM Mark:	Type Approved
Product:	Portable Oxygen Inhaler
Model(s):	AR-001, AR-001A, AR-002, AR-003, AR-003A, AR-004A, AR-005A
Verification to:	Standard: EN 15007:2017 related to CE Directive(s): 2014/68/EU (Pressure Equipment)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Compliance Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. The regulation can be found at www.entecerma.it. This Certificate of Compliance can be checked for validity at www.entecerma.it

This verification doesn't imply assessment of the production of the product(s).

Additional information, clarification about the CE Marking:

We attest that a TCF for the CE Marking process is in place. Whereas the Manufacturer is Responsible to start the CE Marking Certification Procedure through an appointed Notified Body and the perform all the necessary activities, as required by the Directive and accepted by the Notified Body, before placing the CE Mark on the product(s).

Date of issue 23 August 2018

Chief Manager
Matteo Morisi

Expiry date 22 August 2023

Deputy Manager
Amanda Payne

Ente Certificazione Macchine Srl
Via Co' Bello, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
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CE

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Manufacturer:

Xi'an Arooxy Technology Co.,Ltd

European Representative:

Lukáš Paufošima - O2Vigor.cz
Čejkovická 4093/13
628 00 Brno - Czech Republic

Product:

Portable oxygen inhaler

AR-001,AR-002,AR-003,AR-003A,AR-004,AR-005A , AR-001A

Classification: Class I , Rule 1

Conformity assessment Route: Annex II

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF THE FOLLOWING EC COUNCIL DIRECTIVES AND STANDARDS . ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Standard Applied:

EN ISO 14971:2012, EN ISO15223-1:2012, EN14848:2005+AC:2007, EN 15006:2006

Notified Body : **Ente Certificazione Macchine Srl**
ADD: **Via Mincio, 386/a-41056 Savignano s./P. (MO)-ITALY**
NB Identification number: 1282
Start of CE Marking: July 2020
Signature: _____
Name: Cathy Yuan
Position: Overseas Marketing Director
XI'AN ARCOXY TECHNOLOGY CO.,LTD