

# EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Viatom Technology Co., Ltd.  
901, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, P.R. China**

SRN (Manufacturer) **CN-MF-000012182**

Name and address of Authorized Representative: **MedNet EC-REP GmbH  
Borkstrasse 10 , 48163 Muenster, Germany**

SRN (EU Authorised) **DE-AR-000000002**

We declare that the product concerned has been designed and manufactured under a quality management system according to Annex IX of EU 2017/745 (MDR).

Medical Device: **Non-invasive Ventilator  
Model: LeRes-B, R100, LeRes-S, R200, LeRes-C, R10, LeRes-A, R20**

Intended use/purpose: **The device provides positive pressure therapy for the treatment of adult obstructive sleep apnea syndrome in self breathing patients weighing over 30kg (66lbs). This product can be used in the home as well as in clinical/hospital environments. It needs to be used under the guidance of a professional doctor.**

GMDN **42411 Ventilator, adult**

EMDN **Z1203010502 Adult pulmonary ventilators**

Risk class: **Class IIa**

Basic UDI-DI **69344401LeRes-SFU**

Conformity assessment procedure: **EU 2017/745 (MDR) Annex IX (Chapter I + III and Sec.4)**

The EU declaration of conformity is issued under sole responsibility of the manufacturer. We hereby declare that the above mentioned products meet the provisions of the following EUROPEAN PARLIAMENT AND OF THE COUNCIL Regulation and Applicable standards. All supporting documents are retained under the premises of the manufacturer.

Regulations **EU 2017/745 (MDR)  
RED, 2014/53/EU  
ROHS, Directive 2011/65/EU with (EU) 2015/863**

Applicable CS or Standard(s) **EN 60601-1 IEC 60601-1  
EN 60601-1-2 IEC 60601-1-2  
EN 60601-1-11 IEC 60601-1-11  
EN ISO 80601-2-70 ISO 80601-2-70  
EN ISO 80601-2-74 ISO 80601-2-74  
EN ISO 10993-1 ISO 10993-1**

EN ISO 10993-5	ISO 10993-5
EN ISO 10993-10	ISO 10993-10
EN ISO 18562-1	ISO 18562-1
EN ISO 18562-2	ISO 18562-2
EN ISO 18562-3	ISO 18562-3
EN ISO 18562-4	ISO 18562-4
EN 50663	ETSI EN 300 328
ETSI EN 301 489-1	ETSI EN 301 489-17
EN ISO 13485	EN ISO 14971
EN ISO 20417	EN ISO15223-1
EN 62304	IEC 62304

Certificate No.: HZ 2120274-1

Issue date: 2025-7-7

Expiry date: 2029-1-17

Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystraße 2  
90431 Nürnberg  
Deutschland  
CE 0197

Shenzhen, 2025/7/7  
Place, date

  
Zhou Saixin General manager  
Name and function

