



# DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

**Manufacturer:**

Company name: Zhenjiang R&X Technology Co., Ltd.  
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Province, China 212132  
Tel: 0511-83170390  
E-mail: gloria.xu@ryx-tech.com  
SRN: /

**Whose Authorized Representative:**

Name: Lotus NL B.V.  
Address: Koningin Julianaplein 10, 1e  
Verd, 2595AA, The Hague, Netherlands.  
E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

<b>Product Name</b>	Three Balls Spirometer		
<b>Model</b>	RX-1402		
<b>Intend use</b>	This product is used for the recovery of pulmonary respiratory function in patients with chest and lung diseases, surgery, anesthesia, mechanical ventilation and so on, and to reduce and prevent postoperative pulmonary complications.		
<b>CND code</b>	Y030327	<b>Basic UDI-DI</b>	/
<b>Classification and rule</b>	I, rule I	<b>Conformity Assessment Route</b>	Article 19, Annex II and Annex III

**Applicable Standards and CS:**

ISO 13485:2016  
EN 1041:2008

ISO 14971:2019  
ISO 10993-5:2009

EN 15223-1:2016  
ISO 10993-10:2010

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process

Signed:

Name of authorized signatory: Eric Xu

Date: May 11, 2021

Position held in the company: General Manager

Place: Jiangsu, China

Zhenjiang R&X Technology Co., Ltd.