

EC Declaration of Conformity

Manufacturer:

Company name: Zhenjiang Assure Medical Equipment Co.,Ltd
Address: No. 297, Chuqiao Road, Zhenjiang City, Jiangsu Province, China
Tel: +86 511 88896286
Email: info@assuremedical.com.cn

Whose Single Authorized Representative:

Company 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 products Manual Wheelchair meet(s) the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL(MDR) which apply to them.

Item	Product Code	Assure Item Name	Description
1	CS1142T	YJ-012	S1 Steel 18" Wheelchair, Transit
2	CS1142SPMAG	YJ-001D	S1 Steel 18" Wheelchair , 24" SP, Mag Wheels

Assure's SRN	CN-MF-000001076	Lotus' SRN	NL-AR-000000121
BASIC UDI-DI	697423110AS-YJ02-00009U2	UMDNS	17620
Product Group	Wheelchairs, Nonpowered	Classification	I, (MDR, Annex VIII Rule 1)
Intend Use	The device is used for the rehabilitation of the wounded, the sick and the disabled at home, for transportation, medical treatment and outdoor activities.		

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

EN ISO 14971:2012 EN 1041:2008 EN ISO 15223-1:2016
EN 12183:2014 EN ISO 13485:2016 IEC 62366-1: 2015
ISO 7176-19:2008 + A1:2015

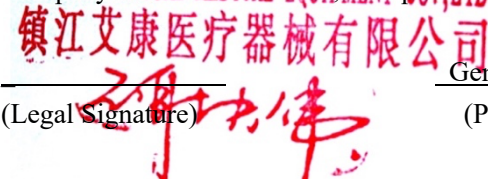
The aforementioned device has been assigned to class I according to Appendix VIII of the Regulation (EU)2017/745. We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745.

The following European Authorized Representative is stated to the declaration:

Company Name: Lotus NL B.V.
Company Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Zhenjiang Assure Medical Equipment Co.,Ltd
Company Address: No. 297, Chuqiao Road, Zhenjiang City, Jiangsu Province, China

镇江艾康医疗器械有限公司



(Legal Signature)

General manager
(Position/title)

2023/08/09
(Date)