



EU DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer

Name : **Zhenjiang Assure Medical Equipment Co.,Ltd**
Address : **No. 297, Chuqiao road, Zhenjiang city, Jiangsu province**
Country : **China**

European Representative

Name : **Lotus NL B.V.**
Address : **Koningin Julianaplein 10, 2595 AA 's Gravenhage**
Country : **The Netherlands**

Product

Product group : **Manual wheelchair**
Model code : **M1//M1 plus**
M5
M6
M9
M1-XL
Compact Lite
Transporter

Classification : **I**
Rule : **According to rule 1**
Category : **11 Assistive products for persons with disability**

We, the manufacturer, herewith declare that the above mentioned products meet the requirements of the Medical Device Regulation (EU) 2017/745 and the following harmonized standards: EN12183:2009; EN ISO 15223-1:2016; EN ISO 14971:2012; EN 1041:2008 & ISO 13485:2016. All supporting documentation is retained at the premises of the European Representative.

Signed for and on behalf of: **Zhenjiang Assure Medical Equipment Co.,Ltd**

Place: **Zhenjiang city**
Date of issue: **21-May-2021**

Signature & Stamp: **ZHENJIANG ASSURE MEDICAL EQUIPMENT CO.,LTD.**
镇江艾康医疗器械有限公司
Name: **XIE FUWEI**
Position: **General Manager**
