

EC Declaration of Conformity

Regarding Medical Device Regulation(2017/745)

Manufacturer:

Name: SiChuan AST Medical Equipment CO. LTD

Address: No.58, Jin-Peng Road, C Area, Luxian Industrial Park, Luzhou City, Sichuan Province, China

SRN: CN-MF-0000001113

Authorised Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

SRN: NL-AR-000000121

We, the manufacturer, herewith declare under our sole responsibility that the products specified meet the provisions of REGULATION (EU) 2017/745.

Name: Wheelchair

Model: AWLAWC007A / AWLAWC011A / LAW007A / LAW011A / LAW001 / WCA2S18SIL

Intended Purpose: A wheeled personal mobility device for a person with a disability or without the full capacity to walk and designed to be manually propelled by the user while seated in the device.

Basic UDI-DI: 697315617LAWC01JY

Classification: I, (Regulation (EU) 2017/745, Annex VIII Rule 1)

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

The Medical devices to which this declaration relates are in compliance with the following standards:

EN ISO 14971:2012 EN 12183:2014 EN 1041:2008 EN ISO 15223-1:2016 EN ISO 10993-1:2018
EN ISO 10993-5:2009 EN ISO 10993-10:2010 EN ISO 9001:2015 EN ISO 13485:2016

Signed for and on behalf of SiChuan AST Medical Equipment Co., Ltd.

Signature:

George Yang

Name: George Yang

Title: General Manager

Place of issue: China, Luzhou

Date of issue: Jul.20th,2021

