

## EU Declaration of Conformity

Manufacturer: Suqian Excellent Science And Technology Co., Ltd.  
Add.: 501 room, Building A, software park, shuyang county,  
Suqian, JiangSu, China  
SRN: CN-MF-000035990  
European Representative: RIOMAVIX SOCIEDAD LIMITADA  
Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain  
SRN: ES-AR-000001202  
Trade Mark: /  
Product Name: Manual Wheelchair  
Model: EXC-2005 EXC-2006 EXC-2007 EXC-2008 EXC-2009 EXC-2010 EXC-2011 EXC-2012 EXC-2013 EXC-2014  
GMDN Code: 41512  
Basic UDI-DI: 697638430EXC07M9  
Intended Use: Mobility tools are used for disabled persons, the sick and the elderly and infirm who weigh no more than 100 kg and have mobility difficulties.

MDR Classification: Class I, According to Rule 1, Annex VIII of Regulation.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Applied standards, common specification, guidance:

EN ISO 15223-1:2021, ISO 20417:2021, EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 13485:2016, MDCG 2019-15, ISO 7176-1:2014.

Signature:

Name:

Position:

Manager

Place/date: China, Jan. 24, 2024



File No.: SQ/CE01-DOC-MW, ver.A/1