EU Declaration of Conformity

Manufacturer:	SunTech UK Ltd. 25 Ormside Way,Holmethorpe Industrial Estate Redhill, Surrey, RH1 2LW,UK
SRN:	Not available
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN:	DE-AR-000000087
Product Name:	eFOLDi Powerchair
Models:	HBLD3-D
GMDN Code:	40840
UMDN Code:	16-214
Basic UDI-DI:	5065002287SUN00717B

Classification (MDR, Annex VIII): Class I, Rule 13.

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, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN 12184:2014, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, IEC 60601-1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+A1:2015, EN 62304:2006+A1:2015.

Signature:

Name: Sumi Wang
Position: General Manager

Place/date: UK, Feb.18th, 2021

CE

File No.: SunTech-MDR/CE02-01-06, ver.A/0