




DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

Manufacturer: Wiseton Industries Limited
Address: No.9 Jiahe Road, Jiashan County, Jiaxing City, Zhejiang Province, P.R. China
UK Responsible Person: SUNGO Certification Company Limited
Address: 3rd floor, 70 Gracechurch Street, London. EC3V 0HR
Product Name: Electric Nursing Bed
Model: B300
Classification: Class I
Conformity Assessment Procedure: Rule 12, Annex IX, Directive 93/42, Part II of the UK MDR 2002

We herewith declare that the above-mentioned products meet the requirements of UK Medical Devices Regulations 2002 and the following standards.

BS EN ISO 20417:2021	BS EN ISO 14971:2019	BS EN ISO 15223-1:2021
BS EN ISO 10993-5:2009	BS EN ISO 10993-1:2020	BS EN ISO 10993-10:2023
BS EN ISO 10993-23:2021	BS EN 60601-1:2006+ A2:2021	
BS EN 60601-2-52:2010+A1:2015	BS EN 60601-1-2:2015 + A1:2021	
BS EN 60601-1-6:2010+A1:2015		

Signature: 

Position: GM

Date: 2025-04-14

Place: Zhejiang/ China

The declaration of conformity is valid in connection with the release technical document UKCA-TCF-003.

All the supporting documentation is retained at the premises of the manufacturer. The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer

