



UE DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 and Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

Manufacturer:

Company name: SILVERFOX CORPORATION
LIMITED
Address: No.18, 1st TongLe Road, TangXia Town,
Pengjiang District, JiangMen City, GuangDong Province,
China
Tel: 0086-750-2633320
E-mail: sales@silverfox.cn
SRN: CN-MF-000008252

Whose Authorized Representative:

Name:: Lotus NL B.V.
Address: Koningin Julianaplein 10,1e
Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@lotusnl.com
SRN:NL-AR-000000121

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Treatment Table		
Model	2211-301, 2211-302, 2211-303, 2211-304, 2211-304F, 2211-308, 2211-PRO		
Intend use	Support the patient's body to keep the formation of clinical need for posture.		
CND code	S08020101	Basic UDI-DI	6973134772211-301LL 6973134772211-302LN 6973134772211-303LQ 6973134772211-304LS 6973134772211-304FN6 6973134772211-308M2 6973134772211-PROVV
Classification and rule	Class I, rule 13	Conformity Assessment Route	Article 19, Annex II and Annex III

Applicable Standards and CS:

ISO 13485:2016, EN ISO 20417:2021, ISO 14971:2019, EN 15223-1:2021
EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO10993-23:2021
IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020
IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
EN 61000-3-3: 2013+ A1:2019+A2:2021
EN IEC 55014-1: 2021
EN IEC 55014-2: 2021
EN IEC 61000-3-2: 2019+A1:2021

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION(EU) 2017/745 and Directive 2014/30/EU. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Chen Yan

Date: MAY 27, 2025

Name of authorized signatory: Chen Yan

Position held in the company: Regulatory Manager

Place: Guangdong, China

SILVERFOX CORPORATION LIMITED

