CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745.

Manufacturer:

Company name: Baoding Sanji Medical Instrument Technology Co., Ltd.

Address: No. 3 Yard, Zhangzhuang Village Industrial Zone, Damafang Township, High-Tech Zone, Baoding City Hebei Province, China

Tel: 0312-3222909

E-mail: carson@sanjimedical.com

Whose Authorized Representative:

Name:: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

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	Tourniquet		
Model	Buckle tourniquet, TPE tourniquet, CAT tourniquet, Esmarch tourniquet, Dialysis tourniquet		
Intend use	The tourniquet is a device that is used to apply pressure to a limb or extremity in order to stop the flow of blood.		
CND code	M0304010101	**Basic UDI-DI**	
Classification and rule	I, rule1	**Conformity Assessment Route**	Article 19, Annex II and Annex III

Applicable Standards and CS:

ISO 13485:2016
ISO 14971:2019
ISO 10993-1:2018
ENISO 10993-5:2009
ENISO 10993-10:2013
EN 1041:2008+A1:2013
EN 15223-1:2016

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

Signed:

Name of authorized signatory: Zhiguang Guo

Date: March 14, 2022

Position held in the company: General Manager Baoding Sanji Medical Instrument Technology Co., Ltd.

Place: Baoding, Hebei , China