EC Declaration of Conformity

Manufacturer:

Anping Guardian Medical Equipment Co., Ltd.
500 meters, Nan Sucun, Anping County,
Hengshui City, Hebei Province, 053600, China

EC Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

Declare under our sole responsibility that the CE Marked medical devices:
Product and Trade Name: Tourniquet
Product Code: see attachment
UDI-DI: see attachment

Classification (MDR EU 2017/745 Annex VIII, Chapter III, 4.1): Class I, Rule 1
Conformity Assessment Route: Annex II and Annex III

Applied Standards:
EN ISO13485:2016, EN ISO 14971:2012, EN 1041:2008, EN ISO 14155:2011
ISO 15223-1:2016, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010

A statement that the device that is covered by the present declaration is in conformity with the Medical Device Regulation / MDR(EU) 2017/745 and other relevant union legislation.

Place and Date: Hengshui City, Aug.31, 2020

Name: LIN YONG

Function: General Manager

Signature: 安平县嘉德医疗器械有限公司 ANPING GUARDIAN MEDICAL EQUIPMENT CO., LTD

Attachment

Product Name	Product Code	UDI-DI
Tourniquet	AZ-G6	6973105230297
	AZ-G7	6973105230303
	AZ-G8	6973105230310
	AZ-TT	6973105230327
	AZ-BT	6973105230334
	AZ-TPT	6973105230341
	AZ-PBT	6973105230358