

Declaration of Conformity

Manufacturer:

EC Representative:

CH Representative:

Anping Guardian Medical Equipment Co., Ltd.

500 meters, Nan Sucun, Anping County,
Hengshui City, Hebei Province, 053600,
China

SRN: CN-MF-000015025

MedNet EC-REP GmbH

Borkstrasse 10, 48163

Münster, Germany

SRN: DE-AR-000000002

MedNet SWISS GmbH

D4 Platz 4 ,6039 Root

D4,Switzerland

Declare under our sole responsibility that the CE Marked medical devices:

Product and Trade Name: Tourniquet

Product Code: see attachment

UDI-DI: see attachment

Basic UDI-DI: see attachment

EMDN Code: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

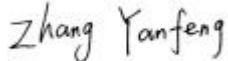
Applied Standards:

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, Jun.14th, 2024

Name: Zhang Yanfeng 

Function: General Manager

Signature: 

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AP-CE-05-01, A1

Attachment

Product Name	Product Code	UDI-DI	Basic UDI-DI	EMDN Code
Tourniquet	AZ-G6	6973105230297	697310523TourniquetU6	V9003
	AZ-G7	6973105230303		
	AZ-G8	6973105230310		
	AZ-TT	6973105230327		
	AZ-BT	6973105230334		
	AZ-TPT	6973105230341		
	AZ-PBT	6973105230358		