

EC Declaration of Conformity

According to Medical Device Regulation / MDR(EU) 2017/745

Manufacturer: Anping Guardian Medical Equipment Co., Ltd.

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

SRN: CN-MF-000015025

EC Representative:MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany

SRN: DE-AR-000000002

Product Information:

Product Name: Tourniquet

Product Code: AZ-G6, AZ-G7, AZ-G8, AZ-TT, AZ-BT, AZ-TPT, AZ-PBT,

Basic UDI: 697310523TQ

UMDNS Code: 14072

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:

ISO13485: 2016,

ISO 14971:2019,

ISO 15223-1:2021, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021,

IEC 62366: 2020, EN 1041:2008+A1:2013,

MEDDEV 2.7/1 rev 4, MEDDEV 2.12/1 rev 8.

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.

The Declaration of conformity is exclusively under the sole responsibility of the manufacturer.

Signature: Yanli Feng **Date:** 2024-02-27

Title: General Manager

Place: Hengshui City

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