

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: Supports

(Medical Splint, Traction Splint, Cervical Collar, Head Immobilizer, Spine Board, Medical Belt, Splint, Stretcher)

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

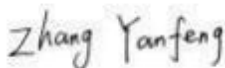
Applied Standards:

EN ISO 13485:2016, EN ISO 14971:2012, EN 1041:2008, ISO 15223-1:2016

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, Dec. 10th, 2024

Name: Zhang Yanfeng



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	Basic UDI-DI	EMDN Code
Medical Splint	AZ-ST	6973105230181	697310523SplintFA	M030502
	AZ-WLP	6973105233663		
	AZ-WST	6973105233670		
	AZ-FCK	6973105233687		
	AZ-MST	6973105233694		
	AZ-AST	6973105233700		
Traction Splint	AZ-TRS	6973105230198	697310523TractionSplint BD	M030502
	AZ-TRS-01	6973105233717		
	AZ-TRS-02	6973105233724		
	AZ-TRS-03	6973105233731		
	AZ-TRS-04	6973105233748		
Cervical Collar	AZ-CC	6973105230204	697310523CervicalColla rAG	M060312
	AZ -AN	6973105230419		
Head Immobilizer	AZ-HI	6973105230211	697310523AZHIHG	Y0606
	AZ-HI-01	6973105232932		
	AZ-HI-02	6973105232680		
	AZ-HI-03	6973105232697		
	AZ-HI-05	6973105230730		
	AZ-HIA	6973105230426		
	AZ-HIA-01	6973105232949		
	AZ-HIA-02	6973105232703		
	AZ-HIA-03	6973105232802		
	AZ-HIA-04	6973105232925		

Product Name	Product Code	UDI-DI	Basic UDI-DI	EMDN Code
	AZ-HIS	6973105230433		
Spine Board	AZ-SP	6973105230228	697310523AZSPJX	Y0603
	AZ-SP-01	6973105232635		
	AZ-SP-02	6973105232642		
	AZ-SP-03	6973105232659		
	AZ-SP-04	6973105232956		
	AZ-SP-05	6973105232666		
	AZ-SP-06	6973105232772		
	AZ-SP-07	6973105232673		
	AZ-SP-08	6973105232765		
	AZ-PB	6973105230440		
	AZ-ED	6973105230457		
Medical Belt	AZ-PSL	6973105230235	697310523AZMBHH	Y122406
	AZ-BAB	6973105230464		
	AZ-ASL	6973105230471		
	AZ-WBA	6973105233755		
	AZ-STW	6973105230488		
	AZ-SSP	6973105230495		
Splint	AZ-SPS	6973105230365	697310523SPLINTPK	M030502
	AZ-FS	6973105230372		
	AZ-TS	6973105230389		
	AZ-ASS	6973105230396		
	AZ-WSP	6973105230402		
Stretcher	AZ-CFS	6973105231645		
	AZ-FST-01	6973105231638		

Product Name	Product Code	UDI-DI	Basic UDI-DI	EMDN Code
	AZ-FST-02	6973105232826	697310523Stretcher5X	V080501
	AZ-FST-03	6973105232833		
	AZ-FST-04	6973105232840		
	AZ-SCP	6973105231621		
	AZ-SCA	6973105232857		
	AZ-BSK	6973105231591		
	AZ-BSK2	6973105231607		
	AZ-STR	6973105231614		
	AZ-LSTR-01	6973105231669		
	AZ-LSTR-02	6973105232819		