

EC Declaration of Conformity

Manufacturer:

EC Representative:

Anping Guardian Medical Equipment Co., Ltd.

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

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany

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

Product and Trade Name: Splint

Product Code: **See Attachment**

UDI-DI: **See Attachment**

UMDNS Code:12-093

Classification (MDR EU 2017/745 Annex VIII, Chapter III, 4.1): Class I, Rule 1

Conformity Assessment Route: Annex II and Annex III

We integrate "HUM Gesellschaft für Homecare und Medizintechnik mbH" as the importer. The



importer Logo is

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, **Mar.13, 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	Factory Product Code	Customer Product Code	UDI-DI
Splint	AZ-R100	HIMT02-SP-XL	06973105230068
	AZ-F100	HIMT02-SP-XL-SET	06973105230075
	AZ-R50	HIMT02-SP-M	06973105230082
	AZ-F50	HIMT02-SP-M-SET	06973105230099
	AZ-F05	HIMT02-SP-XS	06973105230105
	AZ-SET	HIMT02-SP-SET1	06973105230112
	AZ-TR100	HIMT02-SPT-XL	06973105230129
	AZ-TSET	HIMT02-SPT-SET1	06973105230136
	AZ-TF100	HIMT02-SPT-XL-SET	06973105230143
	AZ-T50	HIMT02-SPT-M-SET	06973105230150
	AZ-TF50	HIMT02-SPT-M-SET	06973105230167
	AZ-FS05	HIMT02-SPT-XS	06973105230174