EU 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: Medical Splint

Product Code: See Attachment

Basic UDI: 697310523SPLINTPK

UMDNS Code: 13681

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

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.

We integrate “HUM Gesellschaft für Homecare und Medizintechnik mbH” as the importer. The importer Logo is HUM Systems for Life®

European Importer:

HUM Gesellschaft für Homecare und Medizintechnik mbH

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

Date:12/08/2022

Title: General Manager

Place: Hengshui City

Attachment

Product Name	Factory Product Code	Customer Product Code	UDI-DI
Splint	AZ-R100	HIMT02-SP-XL	6973105230068
	AZ-F100	HIMT02-SP-XL-SET	6973105230075
	AZ-R50	HIMT02-SP-M	6973105230082
	AZ-F50	HIMT02-SP-M-SET	6973105230099
	AZ-F05	HIMT02-SP-XS	6973105230105
	AZ-SET	HIMT02-SP-SET1	6973105230112
	AZ-TR100	HIMT02-SPT-XL	6973105230129
	AZ-TSET	HIMT02-SPT-SET1	6973105230136
	AZ-TF100	HIMT02-SPT-XL-SET	6973105230143
	AZ-TR50	HIMT02-SPT-M	6973105230150
	AZ-T50	HIMT02-SPT-M-SET	6973105230167
	AZ-FS05	HIMT02-SPT-XS	6973105230174