



DECLARATION OF CONFORMITY
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA
Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2026
EN ISO 10993-1: 2025
EN ISO 10993-5:2009+A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021+A1:2025
EN 60601-2-52:2010+A1:2015

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-005.

All the supporting documentation is retained at the premises of the manufacturer.

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

File No.: MDR-TCF-005-08

Manufacturer

Name: HEBEI WEBIAN MEDICAL INSTRUMENT
TRADING CO., LTD
Address: A1-2703 SHIDAI BUILDING, GUANG AN
STREET, CHANG AN DISTRICT, SHIJIAZHUANG CITY,
HEBEI PROVINCE, CHINA
SRN: CN-MF-000031958

Product Information

Name: Guardrail side rail
Model: See Annex
EMDN: V08068099
Basic UDI-DI: 697942410GuardrailZB
Classification: Class I, According to Rule 1, Annex VIII,
Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2025-07-16.

Position: GM Place: Shijiazhuang/China

Annex5

Product Name	Model
Guardrail side rail	HLP-KKSX-10 CTP-JC-1 CTAB-WK-1 CTP-CF-7
	CTAB-WK-03 CTAB-WK-10 CTP-YK-1
	CTP-DH-3 CTAB-WK-05 CTFH-CF-3
	CTABWK-08 CTP-WK-3 CTP-CF-10 CTP-CF-2
	CTFH-CF-1 CTP-CF-9 CTFH-CF-6
	HLAB-HDSX-1 HLP-KKSX-5 HLP-RCZSX-1
	HLP-JSSX-1 HLAB-WKLD-1 HLP-KKLD-1
	HLP-CFLD-1 HLP-CFLD-2 HLP-CFSX-2
	HLP-CFSX-7 HLP-CFSX-8 HLP-CFSX-9
	HLP-KKSX-6 HLAL-CFSX-1 HLP-KKSX-3
	HLP-CFSX-10 HLAL-HCC4-1 HLAL-HCC5-7
	HLAL-ZCC6-2 HLAL-HCC6-7 HLAL-OBC6-1
	HLSS-DHC5-2 HLAL-DFC6-17 HLSS-DFHS-1
	HLSS-QYHS-1 HLSS-DFLD-1 HLSS-XS15-1

