

EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND
OF THE COUNCIL

Doc. No. LY-MRP-008-01

Manufacturer:	Longkou Longyue Medical Device Co., Ltd
Address:	Middle Xufu Street, Longkou, Yantai City, Shandong Province, China
Single Registration Number (SRN) of the Manufacturer:	/
Authorised representative (AR):	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number (SRN) of AR:	DE-AR-000005132
We, the manufacturer, declare under our sole responsibility that :	
The medical device(S)	Product Name: Medical Radiation Protection
	Type/model, identification of product allowing traceability (Where applicable): Lead Apron, Lead Vest And Skirt, Lead Clothing, Lead Thyroid Collars, Lead Gonad Shield, Lead Cap, Lead Glasses, Lead Face Mask, Lead Gloves, Lead Breast Protection, Lead Arm Protection, Lead Hand Protection, Lead Foot Protection, Limbs Protection Articles, Lead Apron Hanger, Dental Radiography Protective Articles, High-Collar Waistcoat Apron, Protective Eyes, Protective Mouth, Oxygen Sack And Ring, Medical X-ray Protective Accessories
	EMDN Code: T0304
	Intended Purpose: It is mainly used for X-ray radiation, scattered radiation protection and shielding protection.
	Classification: (Annex VIII of the MDR) Class I Medical Device according to rule 1
	Basic UDI-DI: /
	Conformity assessment procedure: EC Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post Market Surveillance (Annex III)
Applied harmonized standards and Common Specification: <i>Refer to the Appendix I for details.</i>	
Notified Body: Not Applicable	
Address: Not Applicable	

Notified Body number: Not Applicable
Certificate(s) number.: Not Applicable

The product concerned has been manufactured under a quality management system according to Annex IX of Regulation (EU) 2017/745.

The above-mentioned declaration of conformity was prepared by following the Annex IV of Regulation (EU) 2017/745 and is exclusively under the responsibility of manufacturer.

Longkou Longyue Medical Device Co., Ltd
Address: Middle Xufu Street, Longkou, Yantai City, Shandong Province, China

Appendix I: Applied harmonized standards and Common Specification

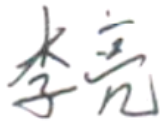
is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification

REGULATION (EU) 2017/745:	EN ISO 13485: 2016+A11:2021
2017+Amended: 2023	
EN ISO 14971: 2019+A11:2021	ISO/TR 24971: 2020
EN ISO 15223-1: 2021	EN ISO 20417: 2021
EN ISO 13688:2013	EN 207:2017
EN 421:2010	MEDDEV2.12/1-rev.8:2013
MEDDEV 2.7/1 rev.4:2016	EN ISO 10993-5:2009
EN ISO 10993-10:2023	EN ISO 10993-23:2021

This DoC is valid from 28 Dec 2023.

Authorized by:



Signature (on behalf of the manufacturer)

Position: General Manager

Rev. 1.0

Signed on: 28 December, 2023.

Place: Longkou, China