## **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

Middle Xufu Street, Longkou, Yantai City, Shandong Address:

Province, China

Single Registration

Number (SRN) of the

Manufacturer:

Authorised representative Share Info GmbH

(AR):

Address: Heerdter Lohweg 83, 40549 Düsseldorf

Single Registration DE-AR-000005132 Number (SRN) of AR:

We, the manufacturer, declare under our sole responsibility that:

**Product** Medical Radiation Protection Name:

Lead Apron, Lead Vest And Skirt, Lead Clothing, Lead Type/model, Thyroid Collars, Lead Gonad Shield, Lead Cap, Lead identification of product allowing Glasses, Lead Face Mask, Lead Gloves, Lead Breast

Protection, Lead Arm Protection, Lead Hand Protection, traceability

Lead Foot Protection, Limbs Protection Articles, Lead (Where applicable): Apron Hanger, Dental Radiography Protective Articles,

High-Collar Waistcoat Apron, Protective Eyes, Protective Mouth, Oxygen Sack And Ring, Medical X-ray Protective

Accessories

T0304 **EMDN Code:** 

> It is mainly used for X-ray radiation, scattered radiation Intended

Purpose: protection and shielding protection.

Classification:

(Annex VIII of Class I Medical Device according to rule 1

the MDR)

Basic UDI-DI:

EC Declaration of Conformity + Technical Documentation Conformity assessment (Annex II) + Technical Documentation on Post Market

procedure:

Surveillance (Annex III)

Applied harmonized

The

medical

device(S)

standards and Common Refer to the Appendix I for details.

Specification:

Notified Body: Not Applicable

Address: Not Applicable

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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 EN ISO 10993-5:2009

rev.4:2016 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

CE