



SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417:2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-AXLB-01.

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.

Manufacturer

Name: Leboo Healthcare Products Limited

Address: A-1506, Lar Valley International No. 168

Guang'anmen Wai St., Xicheng District, 100055

Beijing, P.R. China

SRN: CN-MF-000008521

Product Information

Name: Gowns

Model: N61A01, N61A02, N63B01, N61B01, N61B02, N63A01, N63C01, N61A03, N61A04, N61I01, N61M01, N61A05, N61A06, N61A07, N61P01, N61P02, N61P03, N61B02, N61A0111, N61A0116, N61A0126, N61B0212, N303

EMDN: T0299

Basic UDI-DI: 697442484L03QB

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:

LEBOO HEALTHCARE PRODUCTS

北京安信乐布医疗用

Position: GM

Place: Beijing/China