



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

**EU Representative**

**SUNGO Europe B.V.**  
 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  
 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 CEMDR-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 LIMITED

北京安信乐布医疗用品有限公司

Position: GM

Date: 2023-12-18

北京安信乐布医疗用品有限公司

Place: Beijing/China

