

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **LEBOO HEALTHCARE PRODUCTS LIMITED**
A-1506, Lar Valley International, No.168 Guang'anmen Wai
St., Xicheng District, Beijing 100055, China

Europe Representative: **SUNGO Europe B.V.**
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

We declare under our sole responsibility that

the medical device: **Sterile Surgical Gowns; Sterile Surgical Drapes;**
Sterile Surgical Packs; Sterile Pouches

of class: **Is**
according to annex IX of Directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 93/42/EEC Annex V**

Registration No.: **DD 60141952 0001**
Issue date:2019-08-28
Expiry date: 2024-05-27

Notified Body: **TÜV Rheinland LGA Products GmbH**
Tillystraße 2, 90431 Nürnberg, Deutschland
CE 0197

Report No.: 16803824 008
Issue date: 2019-08-28
Expiry date: 2024-05-27

Application of the above mentioned Annexes and the intervention by the Notified Body is limited to the aspects of manufacture concerned with securing and maintaining sterile conditions.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of Conformity is exclusively under the responsibility of

LEBOO HEALTHCARE PRODUCTS LIMITED
Leboo Healthcare Products Limited
北京安信乐布医疗用品有限公司

Beijing, Aug 29, 2019

/ Place, date /

Guangjun Lu Management Representative

/ Name and function /