EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60124314 0001

Report No.: 16803824 005

Manufacturer:

LEBOO HEALTHCARE
PRODUCTS LIMITED
A-1506, Lar Valley International
No. 168 Guang'anmen Wai St.,
Xicheng District
100055 Beijing
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Surgical Gowns, Sterile Surgical Drapes, Sterile Surgical Packs, Sterile Pouches

Replaces Approval, Registration No.: DD 60114668 0001

Expiry Date: 2019-10-20

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-10-31

Date: 2017-10-31

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.