EC Declaration of Conformity

Manufacturer:

SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road,New District,215153,Suzhou, Jiangsu ,P.R. China

whose single Authorized Representative:

Emergo Europe
Prinsessegracht 20,2514 AP,The Hague,The Netherlands

We, the manufacturer, herewith declare that the products

Disposable Blood Lancets

Type: Twist lancets(Soft,Soft2,SoftTwins,Soft7), Pull top lancets (Clix), Mendor lancets (GlucoMen READY Lancets)Flat white lancets (Soft3, Soft4, Soft5, Soft6)

UMDNS-Code: **10440**; *GMDN-Code:* **61579**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **IIa** according to Annex IX of the Directive 93/42/EEC.
It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex II, excluding Section 4 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60148438 0001
Issue date: 2020-06-01
Expiry date: 2023-02-28

following the procedure relating to the EC Declaration of Conformity set out in Annex II, excluding Section 4 of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

SteriLance Medical (Suzhou) Inc.
No.168 PuTuoShan Road,New District,215153,Suzhou,Jiangsu ,P.R. China

Liu Guohua

Suzhou 2020-06-01
Place , date

Liu Guohua/Quality Manager
Legally binding signature, Function