# EC Declaration of Conformity

*Manufacturer:*

**Chengdu Rich Science Industry Co.,Ltd.**
**Enterprises Registration Address:**
No.66 Tianqindong Street, West Hi-Tech Development Zone,Chengdu，China
**Factory Address:**
No.66 Tianqindong Street, West Hi-Tech Development Zone,Chengdu，China

*whose single Authorized Representative:*

**ENGLOBER LTD.**
**61 De Mijiloc Street, Brasov, Romania**

We, the manufacturer, herewith declare that the products

**Single Use Evacuated Blood Collection Needles**

*UMDNS-Code:* **12736**;

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 designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

**TÜV Rheinland LGA Products GmbH**
**Tillystraße 2, 90431, Nürnberg, Germany**

following the procedure relating to the EC Declaration of Conformity set out in Annex V 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

Company: Chengdu Rich Science Industry Co.,Ltd.
Address: No.66 Tianqindong Street, West Hi-Tech Development Zone,Chengdu，China

Chengdu, January 14, 2016
*Place, date*

*Legally binding signature, Function*

# EC Declaration of Conformity

*Manufacturer:*

**Chengdu Rich Science Industry Co.,Ltd.**
**Enterprises Registration Address:**
No.66 Tianqindong Street, West Hi-Tech Development Zone,Chengdu，China
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*whose single Authorized Representative:*

**ENGLOBER LTD.**
**61 De Mijloc Street, Brasov, Romania**

We, the manufacturer, herewith declare that the products

**Evacuated Blood Collection Tubes**

*UMDNS-Code:* **14183**;

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to In Vitro Diagnostic Medical Devices Directive 98/79/EC. It bears the mark

CE

The product concerned has been designed and manufactured under a quality management system according to In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Compliance of the designated product with the Directive 98/79/EC has been assessed and certified by the Notified Body

**TÜV Rheinland LGA Products GmbH**
**Tillystraße 2, 90431, Nürnberg, Germany**

following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

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

Company: Chengdu Rich Science Industry Co.,Ltd.
Address: No.66 Tianqindong Street, West Hi-Tech Development Zone,Chengdu，China

Chengdu, January 14, 2016
*Place, date*

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