EC Declaration of Conformity

Manufacturer:

Changzhou Shuangma Medical Devices Co., Ltd
San He Kou Development Zone,Zhenglu
Changzhou,Jiangsu 213115
P.R.China

whose single Authorized Representative:

Lotus Global Co.,Ltd
1 Four Seasons Terrace
West Drayton, Middlesex
London, UB7 9GG
United Kingdom

We, the manufacturer, herewith declare that the products

Vaginal Dilators for single use

(including system components and accessories)

UMDNS-Code: **12157**

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 assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60078608 0001
Issue date: 21.09.2012
Expiry date: 20.09.2017

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: Changzhou Shuangma Medical Devices Co., Ltd
Address: San He Kou Development Zone,Zhenglu
Changzhou,Jiangsu 213115
P.R.China

2015/01/31

Place , date

Legally binding signature, Function