

EG-KONFORMITÄT SERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI
CONFORMITÀ

Manufacturer:

whose single Authorized Representative:

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

Landlink GmbH
Dorfstrasse 2/4, 79312
Emmendingen, Germany

We, the manufacturer, herewith declare that the products

Urinary Collection Bags for Single Use
(including system components and accessories)

UMDNS-Code: 14298

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

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



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 60121551 0001

Issue date: 21.09.2017

Expiry date: 20.09.2022

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



Place, date

Legally binding signature, Function