



EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Guilin Woodpecker Medical Instrument Co., Ltd.

MedNet EC-Rep GmbH • Borkstrasse 10 • 48163
Muenster • Germany

We, the manufacturer, herewith declare that
the products **Prophylaxis Powder**, *UMDNS-Code:16699*

MODEL: PT-S1、PT-S2、PT-S3

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

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



The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EEC.

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

The product is in conformity to the following standards:

- | | |
|-----------------------|-----------------------|
| EN ISO 20608-2018; | EN ISO 10993-1: 2009; |
| EN ISO 10993-5:2009; | EN ISO 10993-10:2013; |
| EN 1041:2008+A1:2013; | EN ISO 14971:2012; |
| EN ISO 15223-1:2016; | EN 61025: 2007 |

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

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

Company: **Guilin Woodpecker Medical Instrument Co., Ltd.**

Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi,
541004 P.R.China

马清男 2020.5.22

Preparation , Date

王波 2020.5.22

Review , Date



Legally binding signature, Function