Declaration of Conformity

meets all applicable requirements of the Directive 93/42/EEC Annex I, as ameded by Directive 2007/47/EC

Manufacturer: Shanghai Jianzhong Medical Packaging Co., Ltd.

Add:Bldg 16, 789# Puxing Road Shanghai 201114

declare on our own responsibility that

Medical Device: Product Name: MPACK

Medical Wrapping Nonwoven Sheets

MDD-Classification: Class I

Standard:

Meet all the provisions of the Directive 93/42/EEC on Medical Devices and its latest revisions which apply to it.

Classification:

Classified as class I according to Annex IX of the Directive 93/42/EEC.

Conformity assessment procedure:

Conformity assessment was performed according to Annex $\,^{\mathbb{VI}}$ of the Directive 93/42/EEC.

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:

Name: MedNet GmbH

Borkstrasse 10

48163 Münster, Germany

((

General Manager

宋翌劲

legally binding signature

SHANGHAI 2016/11/29

place, date

Declaration of Conformity

meets all applicable requirements of the Directive 93/42/EEC Annex I, as ameded by Directive 2007/47/EC

Manufacturer: Shanghai Jianzhong Medical Packaging Co., Ltd.

Add:Bldg 16, 789# Puxing Road Shanghai 201114

制造商:

上海建中医疗器械包装股份有限公司

地址: 上海浦星公路789号16幢 邮编201114

declare on our own responsibility that 对以下的声明负责:

Medical Device: Product Name: 医疗器械:

MPACK

产品名称

Medical Wrapping Nonwoven Sheets

MDD-Classification: Class I MDD产品分类 人类

Standard:

Meet all the provisions of the Directive 93/42/EEC on Medical Devices and its latest revisions which apply to it.

Classification:

Classified as class I according to Annex IX of the Directive 93/42/EEC.

Conformity assessment procedure:

Conformity assessment was performed according to Annex III of the Directive 93/42/EEC.

应用标准: 符合医疗器械指令93/42/EEC的所有规定及其适用的最新修订版本。

分类标准:根据附录93/42/EEC. Annex IX 进行医疗产品分类。 符合性认证途径: 符合性认证途径是根据93/42/EEC. Annex Ⅶ。

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:

Name: MedNet GmbH

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SHANGHAI 2016/11/29

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