◆ Declaration of Conformity ◆ CE符合性聲明 ◆ Declaration of Conformity ◆

CE Declaration of Conformity CE

CE符合性聲明

According to the Medical Device Directive 93/42/EEC

按照医疗器械指令93/42/EEC

Manufacturer: 生产商	Anqing Kangmingna Packaging Co., Ltd 安庆康明纳包装有限公司
	Address: 246000 KMN Industrial Park, Jingshi Road, Bridge Development Zone, Anqing, Anhui, China 地址：安徽省安庆市大桥开发区经十路
Authorized representative: 授权代表	Name: KINGSMEAD SERVICE LIMITED Address: 145-157 St John Street, London, EC1V 4PY (UK)
Medical Device: 医疗器械	Product Name: 产品名称

"KMN"® Brand
"康明纳"®

DISPOSABLE STERILIZATION PACKAGING
一次性使用灭菌包装
MEDICAL CREPE PAPER ROLL
皱纹纸
NON-WOVEN SMS/SMMS/SMMMS/ FABRICS ROLL
无纺布
STERILIZATION INDICATOR TAPE/CARD
灭菌指示胶带/指示卡
BOWIE-DICK TEST PACK
B–D测试包
DENTAL BIBS
牙科垫

MDD-Classification: MDD-分类	Class I 级别 I
Lot/batch/Item number: of manufacturer (Where applicable) 生产商的批号/编号	Lot No. 批号 Item No. 编号

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex I of the European Medical Device Directive 93/42/EEC(MDD). Applying ISO13485:2003 Medical Devices - Quality Management Systems and the production is in accordance with EN868 and ISO11607.

兹签字声明以上所列医疗器械符合欧洲医疗器械指令93/42/EEC(MDD)附件1列明的必要要求。
适用ISO13485:2003医疗器械-质量管理体系,并依照欧洲标准EN868和国际标准ISO11607生产。

This declaration of conformity is based on the European Medical Device Directive 93/42/EEC, Annex<v> and is supported by The Certification Body of TÜV PRODUCT SERVICE GMBH, with reference to articles 1 and 3 of the MDD.

参照MDD第1款和第3款,这份符合性声明是基于欧洲医疗器械指令93/42/EEC附件(V)设立,
并受南德意志TÜV认证方的支持。

General Manager:
总经理

ANQING
Mar. 10, 2016

(Place and date of issue)
地点和签发日期

龍其成

(Name and signature or equivalent Marking of authorized person)
声明人签字