

CE Declaration of Conformity CE

CE 符合性声明

According to the Medical Device Directive 93/42/EEC
按照医疗器械指令 93/42/EEC

Manufacturer: Anqing Kangmingna Packaging Co.,Ltd
安庆市康明纳包装有限公司

Address: 246000 KMN Industrial Park, Jingshi Road,
Big Bridge Zone, Anqing, Anhui, China
地址: 安徽省安庆市大桥开发区经十路

Authorized Name: KINGSMEAD SERVICE LIMITED
Representative: Address: 145-157 St John Street, London, EC1V 4PY (UK)
授权代表

Medical Product Name: KMN Brand
Device: HEAT-SEALING STERILIZATION GUSSETET REELS
医疗器械 一次性使用灭菌包装

MDD-Classification: Class I
MDD-分类 级别 I

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex 1 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 TUV 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 TUV 认证方的支持。

General Manager:
总经理

ANQING, JULY.10th, 2020

(Place and date of issue)
地点和签发日期

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

