AMSINO
Advancing Healthcare Worldwide®

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CERTIFICATE of COMPLIANCE

Effective date: 2018-05-02

Customer: ICU Medical BV

P.O. number: 2921

产品代码 Device/Commodity REF No.	产品名称 Product Name	批号 Lot No.	数量 (箱) Qty (CS)	生产日期 Mfg Date	失效日期 Exp Date	灭菌批号 Sterilization Lot No.
0G7199790	22G IV Catheter Sterilized	21-203-KY	240	2020-09	2025-08	2020101903-1
Subtotal (CS)			240CS	/		
Notes: N/A						

兹证明，上述产品的生产过程符合公司产品主文档和相关程序的规定，同时符合 FDA QSR 820，ISO 13485：2016， 以及 MDD 93/42 EEC，2007/47/EC 的规定。 产品经检验符合顾客产品标准和相关适用的协调标准。

This is to certify that the manufacturing process of the above listed device is in compliance with Amsino's DMR and relevant procedures, and in compliance with the applicable requirements of FDA QSR 820, ISO 13485:2016, and MDD 93/42 EEC amended by 2007/47/EC. Products have been inspected and met customer product standards and related applicable harmonized standards:

■ 采用环氧乙烷灭菌产品，灭菌过程确认和常规控制符合 ISO11135：2014 的要求。
For devices sterilized by EtO, the sterilization process and routine control is in compliance with ISO11135:2014.

☐ 采用辐照灭菌产品，灭菌过程确认和常规控制符合 ISO11137-2:2013 的要求。
For devices sterilized by irradiation, the validated sterilization process and routine control is in compliance with ISO11137-2:2013

☐ 非灭菌。
Non-sterile.

上述产品的详细批生产记录留存在美昕医疗器械（上海）有限公司备查。

The DHR (Device History Records) of the above listed devices are maintained at Amsino Medical (Shanghai) Co., Ltd.

批准人 Approved By: _____ 日期 Date: 2020-12-21

职务 Title: QA Manager

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