

**YANGZHOU MEDLINE INDUSTRY CO., LTD.**

No. 108, Jinshan Road, Economic Development Zone, Yangzhou, China

To whom it may concern,

**CERTIFICATE OF CONFORMITY**

The products listed as enclosed had been manufactured according with ISO 13485:2016 and China GMP requirements.

(pls see list as enclosed)

I. Visual Inspection: conform;

II. Functional Inspection: Conform;

III. Sterilization: Conform;

IV. LAL Test (Absence of bacterial endotoxins): Conform;

The visual and functional inspections were completed in accordance with Terumo specifications based on EN/ISO standards.

Sterilization method: EO Sterilization

Sterilization parameters are determined and revalidated periodically according to EN ISO 11135-1.

Sterility Assurance Level (SAL) is  $10^{-6}$ .

The absence of bacterial endotoxins was tested in accordance with USP specifications.



Tanwei  
Manager

Quality Department

YANGZHOU MEDLINE INDUSTRY CO., LTD.

谭伟

**YANGZHOU MEDLINE INDUSTRY CO., LTD.**

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| Product code | Lot No    | Sterilization Date | Exp. Date  |
|--------------|-----------|--------------------|------------|
| MDSS01S2516E | 20201023T | 2020-10-23         | 2025-10-22 |
| MDSS01S2613E | 20201024T | 2020-10-24         | 2025-10-23 |
| MDSS01S2713E | 20201025T | 2020-10-25         | 2025-10-24 |
| MDSS03LE     | 20201027T | 2020-10-27         | 2025-10-26 |
| MDSS05LE     | 20201028T | 2020-10-28         | 2025-10-27 |
| MDSS05S2238E | 20201030T | 2020-10-30         | 2025-10-29 |
| MDSS05S2332E | 20201031T | 2020-10-31         | 2025-10-30 |
| MDSS20ESE    | 20201103T | 2020-11-03         | 2025-11-02 |

