

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.

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2010-TE-6

Product code	Lot No	Sterilization Date	Exp. Date
MDSS01S2516E	20201226T	2020-12-26	2025-12-25
MDSS01S2613E	20201227T	2020-12-27	2025-12-26
MDSS05S2238E	20210106T	2021-01-06	2026-01-05

