

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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2102TE-7&2103TE-3&2014TE-3

Product code	Lot No	Sterilization Date	Exp. Date
MDSS05LE	20210606T	2021-06-06	2026-06-05
MDSS05SE	20210707T	2021-07-07	2026-07-06
MDSS10S2138E	20210516T	2021-05-16	2026-05-15
MDSS05S2138E	20210609T	2021-06-09	2026-06-08
MDSS05S2238E	20210610T	2021-06-10	2026-06-09
MDSS05S2332E	20210611T	2021-06-11	2026-06-10
MDSS20ESE	20210608T	2021-06-08	2026-06-07

