

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.
检验专用章 谭伟



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Product code	Lot No	Sterilization Date	Exp. Date
MDSS01S2516E	20201120T	2020-11-20	2025-11-19
MDSS05S2138E	20201205T	2020-12-05	2025-12-04
MDSS05S2138E	20201204T	2020-12-04	2025-12-03
MDSS05S2332E	20201207T	2020-12-07	2025-12-06
MDSS01SE	20201229T	2020-12-29	2025-12-28

