

888.323.3585 TEL 262.605.3262 FAX

www.twdtradewinds.com

PART #:	REF #:	DESCRIPTION:		LOT #:
DF8088S-ENDO	84011601	ENDOTOXIN-FREE DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL-PACKED.		356575
STERILIZATION DATE: 06/2023			EXPIRATION DATE: 05/2	2028

CERTIFICATE OF STERILIZATION

The validation and routine control of the sterilization process are carried out in accordance with the following standards:

BS EN ISO 11135: 2014	Sterilization of health care products – Ethylene oxide – Part 1: Requirements
	for development, validation and routine control of a sterilizations process for
	medical devices

BS EN 556-1: 2001 Sterilization of medical devices – Requirements for medical devices to be designated "Sterile" – Part 1: Requirements for terminally sterilized medical devices

BS EN ISO 10993-7: 2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Routine control: The criteria for product release from sterilization

- Conformity with the specified physical parameters for the sterilization cycle
- Inactivation of biological indicators

LAL testing is carried out in accordance with the following standards:

GOST ISO 10993-11-2021 Biological evaluation of medical devices Part 11: Tests for systemic toxicity

Provided appropriately stored, products remain sterile for at least 5 years from the sterilization date.

CERTIFICATE OF CONFORMITY

Has been developed, manufactured, inspected and sterilized in accordance with the requirements of:

ISO 13485:2016: Quality systems – Medical devices.

EN ISO 13485:2016: Quality systems – Medical devices.