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PART #:	REF #:	DESCRIPTION:	LOT #:
DF8088S	84011182	DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL- PACKED.	347342
STERILIZATION DATE: 12/2021		EXPIRATION DATE: 11/2026	

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
- No growth of the biological indicators

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:

21 CFR part 820: Quality system regulation.

ISO 13485:2016: Quality systems – Medical devices.

93/42/EEC: Council Directive concerning medical devices

EN 550-1994: Sterilization of medical devices –
Validation and routine control of ethylene oxide sterilization

EN 556-1, 2001: Sterilization of medical devices –
Requirements for medical devices to be designated “Sterile”
Part 1: Requirement for terminally sterilized medical devices