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PART #:	REF #:	DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS		LOT #:
DF8088S	84011600			358232
STERILIZATION DATE: 2024-09-01 (YYYY-MM-DD) EXPI			EXPIRATION DATE: 2029-08-3	1 (YYYY-MM-DD)

## **CERTIFICATE OF STERILIZATION**

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

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

EN 556-1: 2001 Sterilization of medical devices – Requirements for medical devices to be

designated "Sterile" - Part 1: Requirements for terminally sterilized medical

devices

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:

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

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

EN 556-1, 2001: Sterilization of medical devices –

Requirements for medical devices to be designated "Sterile" Part 1: Requirement for terminally sterilized medical devices