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| PART #:                     | REF #:   | DESCRIPTION:                                                                                      | LOT #: |
|-----------------------------|----------|---------------------------------------------------------------------------------------------------|--------|
| DF8088S                     | 84011600 | DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL-PACKED. | 357234 |
| STERILIZATION DATE: 03/2024 |          | EXPIRATION DATE: 02/2029                                                                          |        |

## 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