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<b>PART #:</b>	<b>DESCRIPTION:</b>	<b>LOT #:</b>
<b>DF8088S</b>	<b>DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL-PACKED.</b>	<b>493969</b>
<b>EXPIRATION DATE: 12/2018</b>		

## **CERTIFICATE OF STERILIZATION**

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

- EN ISO 11135-1: 2007 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:

- 21 CFR part 820: Quality system regulation.
- ISO 13485:2003: 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