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PART #:	DESCRIPTION:	LOT #:
DF8088S	DISPOSABLE POLYSTYRENE STERILE BLUE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL-PACKED.	652499
EXPIRATION DATE: 02/2018		

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

Approval Date: 06/03/2013

Michelle Mach
Quality Control Representative