

PART #:	REF #:	DESCRIPTION:	LOT #:	
DF8988P-S-ENDO	84012601	ENDOTOXIN-FREE DISPOSABLE REINFORCED NYLON STERILE WHITE FORCEPS WITH BLUNT TIP. FORCEPS ARE INDIVIDUALLY PEEL-PACKED.	357150	
STERII 17 AT	ION DATE: 03	S/2024 EXPIRATION DATE: 02/20	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

- Inactivation of biological indicators

LAL testing is carried out in accordance with the following standards:

GOST ISO 10993-11-2021 Biological evaluation of medical devices Part 11: Tests for systemic toxicity

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.