



Certificate of Conformance

This certification is provided as full assurance that the following product code and lot number was manufactured in accordance with prescribed procedures and specifications.

Product Part Number:	PEN-01IR
Lot Number:	008083-000
Lot Quantity:	55 CASE(S)
Date of manufacture:	06/17/2018
Shelf Life:	N/A
Description:	CLEANROOM PEN, BLACK, IRR'D (100/CS)
Width:	N/A
Length:	N/A
Irradiation Reference Number:	0001395-00

A handwritten signature in black ink, appearing to read "Paul M. Smith".

06/21/2018

Authorized Signature
Quality Control Department

Date

CC: With Product
Customer File
C of C File

3431 WEST LOMITA BOULEVARD • TORRANCE, CA 90505-5010
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Form No. GEN-1034
REV. No. 01

Certificate Of Processing

Prepared for MICRONOVA MFG INC

STERIS

Gamma Process Run ID 109349A

Product Code

PEN-01IR

Product Lot Number

008083-000

Quantity

55

UOM

CS

Other Information:

0001395-00

Processing Run Start Date/Time: 17-Jun-2018 01:39:17 am

Approx. Downtime (hours): 0.00

Processing Run End Date/Time: 17-Jun-2018 06:30:29 am

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	44.7
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	56.7

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By

✓ **Joanna Jimenez (QS & RC Technician)**

Document Content Revision: 1

Signed On 6/19/2018 at 9:08 AM

UTC / GMT Offset (hh:mm): -7:00

Processing Location:

STERIS
1000 South Sarah Place
Ontario, CA 91761
Phone: 909-390-9942
Fax: 909-390-7854

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.