

CERTIFICATE OF CONFORMANCE

Product Part Number: PEN-01IR
Lot Number: 010540-000
Irradiation Reference Number: 0001818-000
Lot Quantity: 80 CASE(S)
Date of manufacture: 10/28/2018
Shelf Life: N/A
Description: CLEANROOM PEN, BLACK, IRR'D (100/CS)
Size -
Width: N/A
Length: N/A
Height: N/A

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



Authorized Signature
Quality Control Department

10/30/2018

Date

CC: With Product
Customer File
C of C File

Certificate Of Processing

Prepared for MICRONOVA MFG INC



Gamma Process Run ID **111757A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
PEN-01IR	010540-000	80	CS

Other Information:

0001818-00

Processing Run Start Date/Time:	27-Oct-2018 07:13:14 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	28-Oct-2018 01:56:19 am		

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	43.0
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	57.7

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 10/29/2018 at 11:25 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.