



CERTIFICATE OF CONFORMANCE

Product Part Number: PEN-01IR
Lot Number: 037963-000
Irradiation Reference Number: 0007500-00
Lot Quantity: 80 CASE(S)
Date of manufacture: 05/10/2023*
Shelf Life: 24 MONTHS
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.

5/22/2023

Authorized Signature
Quality Control Department

Date

CC: With Product
Customer File
C of C File

***Refer to Certificate of Processing for irradiation complete date**

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Form No. GEN-1034e
REV. No. 02

STERIS: Gamma Certificate Of Processing

Prepared for: MICRONOVA MFG INC (2727)

Gamma Process Run ID 1113-14936A

Product Code

Lot Number

Quantity

UOM

PEN-01IR

037963-000

80

Case

Processing Run Start Date: 19-May-2023 10:23 PM

Approx. Downtime (hours): 0.67

Processing Run End Date: 20-May-2023 5:03 AM

Minimum Specified Dose (kGy): 25.0

Minimum Delivered Dose (kGy): 27.6

Maximum Specified Dose (kGy): 40.0

Maximum Delivered Dose (kGy): 36.4

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

Other Information

0007500-00

Signature Manifest

Reviewed and E-Signed By: **Joanna Jimenez (Senior Quality Technician)**

Date/Time E-Signed: 21-May-2023 2:33 PM

Document Content Revision: 1

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 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137:2017. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.

Processing Location

1000 Sarah Place
Ontario CA 91761
United States

Product Code

Lot Number

Quantity UOM

APPROVED

By Noel Chaidez at 9:35 am, May 22, 2023