



CERTIFICATE OF CONFORMANCE

Product Part Number: PEN-01IR
Lot Number: 037316-000
Irradiation Reference Number: 0007358-00
Lot Quantity: 80 CASE(S)
Date of manufacture: 03/24/2023*
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.

4/3/2023

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 1113-14262A

Product Code

Lot Number

Quantity

UOM

PEN-01IR

037316-000

80

Case

Processing Run Start Date: 02-Apr-2023 2:38 AM

Approx. Downtime (hours): 0.07

Processing Run End Date: 02-Apr-2023 10:28 AM

Minimum Specified Dose (kGy): 25.0

Minimum Delivered Dose (kGy): 26.9

Maximum Specified Dose (kGy): 40.0

Maximum Delivered Dose (kGy): 34.7

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

Other Information

0007358-00

Gamma Process Run Approval authorized by STERIS

Date/Time E-Signed: 02-Apr-2023 4:11 PM

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

APPROVED

By Noel Chaidez at 11:34 am, Apr 03, 2023

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