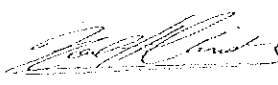




CERTIFICATE OF CONFORMANCE

Product Part Number: PEN-01IR
Lot Number: 011792-000
Irradiation Reference Number: 0002081-00
Lot Quantity: 80 CASE(S)
Date of manufacture: 01/20/2019
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

01/22/2019

Date

CC: With Product
Customer File
C of C File

3431 WEST LOMITA BOULEVARD • TORRANCE, CA 90505-5010 Tel. (310) 784-6990 • FAX (310) 784-6980

STERIS (01/1/2019) 11/11/2019

Prepared for: MHC/RC/VA MHC/RC

Processing Process: Run ID: 113132A

Product Code	Product Lot Number	Quantity	UOM
EN-01R	011792-000	30	CS

Other Information:

0002081-00

Processing Run Start Date/Time:	19-Jan-2019 10:55:16 pm	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	20-Jan-2019 03:05:31 am		

Minimum Specified Dose (kGy):	40.0	Minimum Delivered Dose (kGy):	44.1
Maximum Specified Dose (kGy):	60.0	Maximum Delivered Dose (kGy):	55.5

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

Signature Manifest

Reviewed and E-Signed By
Rony Mejia (QS/RC Analyst)
Document Content Revision: 1

Signed On 1/21/2019 at 10:09 AM
UTC/GMT Offset (hh:mm) -3:00

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/AMMISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used.