



Certificate of Conformance and Sterility

This certification is provided as full assurance that the following product code and lot number were manufactured in accordance via a Quality System certified to ISO 9001 with prescribed procedures and specifications.

Product Code:	MEQT0022
Lot Number:	1010304-0-0-1
Manufacturing Date:	08/11/2023
Expiration Date:	08/2025

Sterility

Gamma Processing Run ID:	1153-8518A
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	29.1 kGy to 44.3 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

A handwritten signature in black ink, appearing to read "C. Duffee".

QC Supervisor
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Monday, August 28, 2023

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DID: 20498A

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC INC (1963)

Gamma Process Run ID 1153-8518A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
492238-955	1012509-0-0-1	18	Case
HCMT0015	1012424-0-0-1	72	Case
HCMT0015	1012425-0-0-1	72	Case
HCMT0015	1012426-0-0-1	72	Case
HCMT0015	1012427-0-0-1	72	Case
LWCS0027	1012497-0-0-1	36	Case
LWPS0006	1012007-0-0-1	54	Case
MEQT0022	1010304-0-0-1	48	Case

Processing Run Start Date: 25-Aug-2023 9:41 AM

Processing Run End Date: 25-Aug-2023 7:59 PM

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	29.1
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	44.3

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

Gamma Process Run Approval authorized by STERIS

Date/Time: 26-Aug-2023 6:32 AM

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 11137-1:2015.

Processing Location

2072 Southport Road
Spartanburg, SC 29306
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Phone: 864-582-3041