

STERILE DRAPES – CERTIFICATE OF CONFORMANCE AND STERILITY

1089 STERI DRAPE UTILITY DRAPE 2/PKG 80 PKG/CASE

PRODUCT NAME

70-2004-1289-1

PRODUCT NUMBER

2025-09 DB

OUTPUT LOT NUMBER

16 CS

OUTPUT QUANTITY (TOTAL CASES)

6917

EO STERILIZATION LOAD NUMBER

This letter certifies that the product listed on this certificate has:

A) Been manufactured in accordance with "Good Manufacturing Practices for Medical Devices and Humane

Services FDA, QSR Federal Register 21 CFR Part 820. B, and ISO 13485.

B) Been manufactured in accordance with 3M Healthcare specifications.

C) Been released as sterilized material with a sterility assurance level of at least 10⁻⁶ based on review of the Certificate of Processing issued by Steris-Isomedix Site 2, El Paso, TX 79936, USA. All processing parameter specifications related to the sterilization process have been met and all biological indicator results were reviewed and determined to be acceptable.

D) Been sterilized according to the effective version of EN 556, ST 67, and ISO 11135.



3M Health Care Business

3M EDUMEX – Quality Control

EDUMEX SA DE CV

JUAREZ, MEXICO 32690

QA/QC REPRESENTATIVE

Raymundo Castrejon

DATE

APRIL/04/2024

INV#/REQ#:

N/A

CUSTOMER:

3M HEALTHCARE.