

CERTIFICATE OF ANALYSIS

PRODUCT PO0678D PRO-TECT C/PLATE (X3 WRAP + IRRAD)

LOT NUMBER 6258091

EXPIRY DATE 2025.07.14 **TEST DATE** 2025.04.10 **REPORTING DATE** 2025.04.15

| General Characteristics | Results | | Specification |
|--|---------------|-------------|--------------------------------------|
| Colour | Conforms | | Straw |
| Appearance | Conforms | | Transparent |
| pH | 7.4 | | 7.1 -7.5 |
| Packaging / Presentation | Conforms | | 10 plates, triple-wrapped |
| Average irradiation dose (kGy) | 14.51 | | 11.50 - 22.00 |
| Cont. check @ 20-25 & 30-35°C for >=120h | Conforms | | No Contamination |
| Microbiological Performance | Control c.f.u | Test Result | Specification |
| Incubation @ 30-35°C up to 72h, aerobic | | | |
| Escherichia coli ATCC®8739 | 97 | 85 | 3-5mm, cream colonies |
| Staphylococcus aureus ATCC®6538 | 83 | 76 | 1-3mm, straw colonies |
| Pseudomonas aeruginosa ATCC®9027 | 84 | 89 | 2-5mm, straw colonies |
| Bacillus subtilis ATCC®6633 | 86 | 73 | 3-9mm, irregular straw colonies |
| Incubation @ 32°C up to 48h, anaerobic | | | |
| Clostridium sporogenes ATCC®19404 | 100 | 103 | 1-2 mm, grey to cream coloniess |
| Incubation @ 20-25°C up to 72h, aerobic | | | • • • |
| Bacillus subtilis ATCC®6633 | 86 | 67 | 3-9mm, irregular straw colonies |
| Incubation @ 20-25°C up to 120h, aerobic | | | - |
| Candida albicans ATCC®10231 | 56 | 66 | 2-3mm, cream colonies |
| Aspergillus brasiliensis ATCC®16404 | 31 | 22 | 10-30mm, white mycelia, black spores |

Colony counts shall be equal to or greater than 50% of the control medium (Tryptone Soya Agar or Sabouraud Dextrose Agar)

Tested in accordance with the methods described in the current United States pharmacopoeia for the microbiological control and monitoring of aseptic processing environments.

The information given is believed to be correct. However, both the information and the product are offered without warranty for any specific application other than that specified. The results reported were obtained at the time of release.

This certificate is produced electronically and valid without a signature



The quality control methods meet requirements of ISO 11133.