

## CERTIFICATE OF ANALYSIS

<b>PRODUCT</b>	<b>PO5511D</b>	<b>TRIPLE WRAP STERILE TSA+NEUTR.CONTACT</b>
<b>LOT NUMBER</b>	6278646	
<b>EXPIRY DATE</b>	2026.03.31	
<b>TEST DATE</b>	2025.06.12	
<b>REPORTING DATE</b>	2025.06.17	

General Characteristics	Results	Specification
Colour	Conforms	Ivory
Appearance	Conforms	Transparent
pH	7.3	7.1 -7.5
Packaging / Presentation	Conforms	Conforms to specification
Average irradiation dose (kGy)	15.56	13.00 - 22.00
Cont. check @ 20-25 & 30-35°C for >=120h	Conforms	No Contamination

Microbiological Performance	Control c.f.u	Test Result	Specification
Up to 3 days @ 30 - 35°C			
Escherichia coli ATCC®8739	96	83	2-10 mm, cream colonies.
Staphylococcus aureus ATCC®6538	89	94	1-2 mm, cream, shiny colonies.
Pseudomonas aeruginosa ATCC®9027	55	65	3-8 mm, green-yellow colonies.
Bacillus subtilis ATCC®6633	64	55	4-8 mm, cream colonies.
Staphylococcus epidermidis ATCC®12228	95	91	1 mm, cream colonies.
Kocuria rhizophila ATCC®9341	71	79	0,5-0,75 mm, yellow colonies.
Up to 2 days @ 32°C, anaerobic			
Clostridium sporogenes ATCC®19404	51	52	1-2 mm, cream colonies.
Up to 5 days @ 30 - 35°C			
Candida albicans ATCC®10231	75	76	2 mm, cream colonies.
Aspergillus brasiliensis ATCC®16404	22	24	10-30 mm, white mycelium, black spores.
Up to 3 days @ 20 - 25°C			
Bacillus subtilis ATCC®6633	64	56	4-8 mm, cream colonies.
Up to 5 days @ 20 - 25°C			
Candida albicans ATCC®10231	75	64	2 mm, cream colonies.
Aspergillus brasiliensis ATCC®16404	22	25	10-30 mm, white mycelium, black spores.

Moderate to heavy growth of the tested organisms. Recovery greater than 50% and less than 150% of the control and is comparable to a previously released batch.

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

The quality control methods meet requirements of ISO 11133.



The testing laboratory of Oxoid Deutschland GmbH is accredited by the German accreditation body DAKKS according to DIN EN ISO/IEC 17025 for the performance testing of media for microbiology to DIN EN ISO11133 and registered under D-PL-20190-01-00.

## **CERTIFICATE OF ANALYSIS**

**Sterility Assurance Level:**

This product has been terminally sterilized to a SAL level of  $10^{-5}$  by irradiation exposure to be within 13.0 - 22.0 kGy.

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.



The testing laboratory of Oxoid Deutschland GmbH is accredited by the German accreditation body DAkkS according to DIN EN ISO/IEC 17025 for the performance testing of media for microbiology to DIN EN ISO11133 and registered under D-PL-20190-01-00.