



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

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**Certificate of Responsible Analyst**

Issued under subregulation 29 (1) of the *Therapeutic Goods Regulations 1990*

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A sample of therapeutic goods, bearing TGA sample number 2102000836 has been examined and analysed

The sample was submitted by S&T (QLD)

Results are applicable to the sample tested, as received by the TGA Laboratories Branch.

The goods were represented to be:

**ARTG Number:** 338674  
**Name:** N95 Particulate Respirator N95 FT-N058  
**Sponsor:** Bunzl Australia  
**Batch Number:** YCFT2020006  
**Expiry Date:** 31-August-2023  
**GMDN:** Surgical/medical respirator, single-use (57794)

TEST	RESULT	REQUIREMENT
<b>Visual Inspection (Medical Device)</b>		
- Information	Not Assessed	INFORMATION provided meets the requirements of EP13
- Design	Yes	DESIGN is consistent with the intended purpose
- Marking	Not Assessed	MARKING meets requirements of EP13 and is consistent with the intended purpose
- Quality	Yes	QUALITY: Samples inspected did not present notable defects or variability

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This Certificate has been signed and issued electronically by the Responsible Analyst nominated under subregulation 25(3)(c) of the *Therapeutic Goods Regulations 1990*

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TEST	RESULT	REQUIREMENT
<b>Resistance Against Penetration by Synthetic Blood (ISO 22609:2004)</b>		
- Area Targeted	Main Body	ISO 22609:2004 (Testing conducted with targeting plate under ambient conditions)
- Pressure	120 mmHg	
- Masks Tested	32 Masks	ISO 2859-1:1999 Single sampling plan = 32 Double sampling plan = 20/40
- Failed Masks	0 Masks	
- Result	Pass	ISO 2859-1:1999 Sample size G, AQL 4%, Normal Inspection
<b>Screening Respirator Penetration Efficiency KN95/N95 (95%)</b>		
- Minimum Filter Efficiency	99.7 %	>= 95.0 %
- Maximum Filter Efficiency	99.9 %	>= 95.0 %
- Initial Filter Resistance	11.0 mmH20	<= 35.0 mmH20
- No of Units Tested	10	
- Units below PFE limit	0	

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**TGA** Health Safety  
Regulation