



GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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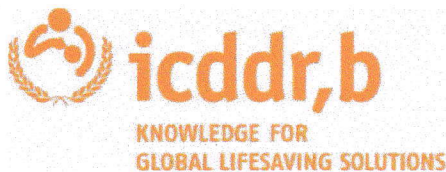
Specifications and Quality Control (QC) parameters for Coveralls (fluid resistant, disposable, with elastic wrists, ankles and hood)

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Supported by



Coveralls, fluid resistant, disposable, with elastic wrists, ankles and hood

WHO Recommendation as minimum standard:

- **Option 1:** blood and body fluid penetration resistant: meets or exceeds ISO 16603 class 4, 5 or 6 exposure pressure, or equivalent
- **Option 2:** blood-borne pathogens penetration resistant: meets or exceeds ISO 16604 class 4, 5 or 6 exposure pressure, or equivalent
- Breathability of RET less than 30 m2Pa/W according to ISO 11092, or equivalent

Supporting Standards/Guidelines

- ISO 16603:2004(en)
- ISO 16604:2004(en)
- ISO 11092:2014
- ASTM F1670 – 98
- ASTM F1671 - 97b
- AAMI PB70
- BS EN 13795:2019 or equivalent standard

Possible Test Parameters

- Water vapor transmission (breathability)
- Viral Penetration
- Synthetic Blood Penetration
- Water Resistance: Hydrostatic Test
- Tensile Strength
- Tear resistance
- Seam Strength
- Water Resistance: Impact Penetration Test
- Lint Generation

Testing parameters and specifications for Coveralls (fluid resistant, disposable, with elastic wrists, ankles and hood)

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per AAMI Standards)				Remarks/References
			Level 1 (minimal)	Level 2 (low)	Level 3 (moderate)	Level 4 (high)	
1.	Tensile Strength (ASTM D5034, ASTM D1682)	N	≥30N	≥40N	≥50N	≥80N	
2.	Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), EN 14325-2018)	N	≥10N	≥15N	≥20N	≥20N	
3.	Seam Strength (ASTM D751 (stretch woven or knit), ASTM F3352-19; or equivalent)	N	≥30	≥30	≥30	≥30	
4.	Water vapor transmission (breathability) (ISO 11092:2014(EN); ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75; or equivalent)	Water Vapor Transmission m ² Pa/W (=Ret)	-	-	<30	<30	This criteria is optional, to comply the optional criteria the manufacturer has to mention the breathability status of coveralls as Breathable /Non-breathable
5.	Water Resistance: Hydrostatic Test (AATCC 127; BS EN 13795:2019)	cm H ₂ O	N/A	>20	>50 (sterile) >57.3 (fluid resistant)	>100 (sterile) >91 (fluid resistant)	
6.	Water Resistance: Impact Penetration Test (AATCC 42 or equivalent)	g	≤4.5	≤1	≤1	≤1	
7.	Synthetic Blood Penetration Test (ASTM F1670 or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	* PPE importers must present relevant documents and certification
8.	Viral Penetration Test (ASTM F1671 or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	

* Acceptance Quality Limit: AQL 4%

*** The alternate protocol/provision is allowed temporarily until test facilities are developed and established locally, as per proposed standard(s).

Appendix

Packaging:

- All surgical items must be supplied sterile;
- Must be individually packaged;
- Must contain within the packaging a sterile field to open the gown onto;
- Must be folded with the inside facing outward and the collar visible, the wearer must be able to don the gown without touching the patient facing side;
- Must be latex free (surgical or no-surgical);
- Must be antistatic;
- Must have product specification sheet;
- Must have SOP to use and to dispose.