



## Disposable cleanroom garments CleanTough Material

PPE category Type 5 & 6



BioClean™-D garments provide the wearer superior comfort and maximum protection. . The garments are manufactured from a revolutionary Clean-Tough fabric which is **antistatic**, lightweight, hard-wearing.

It is compatible for use in ISO Class 4 cleanrooms / GMP grade A.

All garments are available as sterile and non-sterile.

Available BioClean™-D garments:

- Overall with and without hood
- Lab coat
- Hood
- Sleeve cover
- Overboots (sole not antistatic)

### **Quality standards:**

- Manufactured in a facility holding ISO 9001: 2015 and (EU) 2016/425 module D certifications
- Conforms to category 3 – Personal Protective Equipment PPE Regulation (EU) 2016/425
- Tested against standard EN ISO 13982-1: 2004 + A1: 2010 protective clothing for use against solid particles (Type 5)  
Tested against standard EN ISO 13034: 2005 + A1: 2009 protective clothing against liquid chemicals (Type 6)
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against permeation standard ASTM F739-12
- Tested against standards: EN1149-5: 2008 \*, protective clothing - electrostatic properties; EN 530, abrasion resistance; EN 7854, flex cracking resistance; EN 6530, resistance to penetration by liquids; EN13934-1, tensile strength; EN 9073-4, trapezoidal tear resistance; EN 863, puncture resistance; EN 13935-2, seam strength
- Processed in an NEBB certified ISO class 4 environment

\* NOTE: BioClean™ CleanTough-Material is static dissipative, with a charge half decay time of 0,07 sec. and so are ideal for use in a static-safe environment.

**Shelf life / Storage:** 5 years resp. 3 years (sterile) from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

**LOT-Number:** Shown on each individual bag and carton to provide product traceability.



## Performance test results – BioClean™-D CleanTough white material

Test:	Results:	Performance class (EN 14325)
Abrasion resistance	10 – 100 cycles	1
Flex cracking resistance	5.000 – 15.000 cycles	3
Trapezoidal tear resistance	MD 55.5 N CD 29.3 N	3 2
Tensile strength	MD 97 N CD 48 N	2 1
Puncture resistance	8 N	1
Seam strength *2	70 N	2
Repellence to liquids	30% H <sub>2</sub> SO <sub>4</sub> 96,3%	3
	10% NaOH            97,6%	3
	O-Xylene             95,7%	2
	Butan-1-ol            96,6%	3
Penetration by liquids	30% H <sub>2</sub> SO <sub>4</sub> 0%	3
	10% NaOH             0%	3
	O-Xylene              0%	3
	Butan-1-ol             0%	3
Inward leakage of aerosols of fine particles*1	Pass	N/A
Resistance to penetration by spray (Spray-Test) <sup>1</sup>	Pass	N/A
Electrostatic charge half decay time, T <sub>50</sub> (sec.)	0,07	Pass

\*1 All interfaces with additional PPE were taped during testing, as required by the standards

\*2 Seams not destroyed                                      N/A not applicable

### Particle shedding test results

Test:	Result:	Category (IEST-RP-CC003.3)
Particle shedding (Helmke Drum Test)	<2000	Cat. 1

### BioClean™-D CleanTough white material - ASTM F739-12 – Test method results

Mean breakthrough time(MBT), minutes

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0,1 µg/cm<sup>2</sup>/min.

Cisplatin	Carmustine	Cyclophosphamide	Doxorubicin hydrochloride
>240	<6	217 (275, 162, 215)	>240

5-Fluorouracil	Methotrexate	Etoposide	Paclitaxel	Tiotepa
>240	>240	>240	<10	30 (28, 30, 33)

**hans j. michael gmbh**

Gewerbegebiet Hart 11, D-71554 Weissach i.T., Phone: 0049-7191-9105-0, Fax: 0049-7191-9105-19  
e-mail: [office@hjm-reinraum.de](mailto:office@hjm-reinraum.de), website: [www.cleanroom-hjm.com](http://www.cleanroom-hjm.com)