Annex 4

Comparison of Medical Protective Clothing Standards

The result of comparison between China's mandatory national standard GB 19082-2009 technical requirements for disposable protective clothing for medical use and the EU standard (EN 14126) is as follows. This result is summarized through the materials of standard comparison provided by Medical Device Standard Management Center of China Medical Products Administration, Science and Technology Development Department of China National Textile Industry Federation, National Technical Committee for Personal Protective Equipment Standardization and other relevant parties.

For scope of application：

EN 14126 applies to reusable anti-virus protective clothing.

GB 19082 applies to medical disposable protective clothing for medical personnel who come into contact with potentially infectious patients' blood, body fluids, secretions and airborne particles to provide barrier and protection.

For physical properties of fabric：

EN 14126 refers to EN 14325, *Chemical Protective Clothing* -

Chemical Protective Clothing Materials, Seams, Joints and the Test Method and Properties Classification of Components. EN 14325 requires that protective clothing should be tested and classified according to the fabric test methods and fabric performance classification system determined by the standard.

GB 19082 specifies two indexes such as elongation at break and fracture strength. Other indexes such as wear resistance, flexural resistance, flexural resistance (-30℃) and tear are not specified.

For barrier properties of fabric:

EN 14126 mainly refers to international standard such as ISO 16603, ISO 16604, ISO 26610, ISO 26611 and ISO 26612. EU standard specifies the classification requirements in five aspects including anti-synthetic blood penetration, anti-blood-borne pathogen (Phi-X174) bacteriophage contaminated liquid pressure penetration test, anti-wet microbial penetration test, anti-microbial aerosol test, and anti-dry microbial test.

GB 19082 mainly specifies the requirements of the water resistance test, water testing, particle filtration efficiency and moisture permeability.

For overall clothing performance:

EN 14126 mainly specifies three indicators, namely, overall clothing performance test, joint strength and skin irritation, among which the

overall clothing performance refers to relevant international standards and EU standards such as EN466. They are divided into protective suits against liquid aerosol and solid particles, liquid dense protective suits (Type3), spray dense protective suits (Type4), protective suits against solid particles (Type5), and protective suits against slight chemical liquid splash (Type6).

GB 19082 specifies six indicators, including requirements for microbial indicators, sterilization requirements, residual ethylene oxide, antistatic property, electrostatic attenuation and skin irritation.

Comparison of key requirements from two standards is listed in table 4-1.

Table 4-1 Comparison of Key Technical Requirements from EN 14126:2003 and GB 19082-2009

Standard Number		GB 19082-2009		EN 14126:2003	
Standard Name		Technical Requirements for Disposable Protective Clothing for Medical Use		Protective Clothing - Performance, Requirements and Test Methods for Anti-virus Protective Clothing	
Scope		The standard standardizes the requirements for disposable protective clothing for medical use. This standard is applicable to medical disposable protective clothing for medical personnel who come into contact with potentially infectious patients' blood, body fluids, secretions and airborne particles to provide barrier and protection. Applications: medical disposable protective clothing		The standard standardizes the requirements and test methods for reusable, limited-use anti-virus protective clothing. The standard does not apply to protective clothing worn by first-line surgical personnel or surgical orders placed on the patient's body to prevent cross-contamination during surgical intervention. Applications: Anti-infective-substance protective clothing	
Technical Terms		**Index Requirements**	**Test Methods**	**Index Requirements**	**Test Methods**
Physical Properties of Fabric	Abrasive Resistance	None		Mechanical and flammability requirements: materials shall be tested and classified in accordance with the test methods and performance classification system standardized under the relevant provisions of pr EN 14325.	
	Flexing Resistance	None			
	Flexing Resistance at -30℃ （Optional）	None			
	Tear Resistance	None			
	Elongation at Break	Key parts should not be less than 15%	GB/T 3923.1-1997		
	Fracture Strength	Key parts should not be less than 45N	GB/T 3923.1-1997		
Barrier	Impermeability	The hydrostatic pressure	GBT 4744-1997	None	

Properties of Fabric	Test	of key parts should be ≥ 1.67kpa			
	Water Test	≥Level 3	GBT 4745-1997	None	
	Particle Filtration Efficiency	The filtration efficiency of Nacl at key parts and joints should be no less than 70%	Article 5.7 of GB 19082-2009	None	
	Moisture Transmission	≥2500g/(m^2·d)	Method A of GB/T 12704-1991	None	
	Resistance to Synthetic Blood Penetration	Level 1（0kPa） Level 2（1.75kPa） Level 3（3.5kPa） Level 4（7kPa） Level 5（14kPa） Level 6（20kPa） Should not≤Level 2	Annex A to GB 19082-2009	Level 1（0kPa） Level 2（1.75kPa） Level 3（3.5kPa） Level 4（7kPa） Level 5（14kPa） Level 6（20kPa） Classifivation according to actual test results.	ISO 16603
	Pressure penetration test of contaminated liquid against blood-borne pathogen (phi-x174) bacteriophage	None		Level 1（0kPa） Level 2（1.75kPa） Level 3（3.5kPa） Level 4（7kPa） Level 5（14kPa） Level 6（20kPa） Classification according to actual test results.	ISO 16604
	Resistance to Moisture Microbe Penetration	None		Level 1（≤15min） Level 2（15<t≤30min） Level 3（30<t≤45min） Level 4（45<t≤60min）	ISO 26610

				Level 5（60<t≤75min） Level 6（t>75min） T is the breakthrough time	
	Anti-microbial Aerosol Test	None		Level 1（1<log≤3） Level 2（3<log≤5） Level 3（log>5） Log is penetration	ISO 26611
	Anti-dry Microbe Test	None		Level 1（2<log cfu ≤3） Level 1（1<log cfu ≤2） Level 3（log cfu ≤1） Log cfu is the penetration index	ISO 26612
Overall Clothing Performance	Overall Clothing Performance Test	None		Specific requirements refer to other EN standards: ——Type 1 EN 943-1（EN943-2 for emergency team (ET) "airtight" chemical protective clothing）， ——Type 3 EN 466 ——Type 4 EN 465， ——Type 5 ISO 13982-1， ——Type 6 EN 13034 ——Partial body protection EN 467	
	Seam Strength	None		EN 14325	
	Microbiological Index Requirements	There are requirements for bacterial colony detection	Annex B to GB 15979-2002	None	
	Sterilization Requirements	Sterilized and non-sterilized. If sterilized, the words "sterile" shall be marked on the package		None	
	Residual	Should not exceed	Article 5.13 of	None	

	Ethylene Oxide	10μg/g	GB19082-2009	
	Skin Irritation	The primary stimulus score should not exceed 1	Article 5.11 of GB19082-2009	Article 4.3 of EN14126 requires that materials and designs used shall not cause skin irritation or adverse health effects.
	Antistatic Property	The electric quantity of protective clothing should not exceed 0.6μC/piece	Article 7.2 of GB/T 12703-1991	None
	Static Decay	The static decay time of protective clothing should not exceed 0.5s.	Article 5.10 of GB19082-2009	None

Note: The comparison provided is only technical information based on text comparison and cannot be used as a legal basis for the foreign party to choose Chinese products.