Annex 3

Comparison of Single-use Medical Rubber Gloves Standards

Single-use medical rubber gloves are mainly used for medical examination and diagnosis, to prevent cross-infection between patients and users during surgical operation, and to handle contaminated medical materials. At present, Single-use medical rubber gloves produced in China include three types: single-use medical rubber inspection gloves, single-use sterilized rubber surgical gloves and single-use non-sterilized rubber surgical gloves.

The main technical requirements of single-use medical rubber gloves are classifications, material requirements, dimensions, tensile properties, water-tightness, sterilization, sampling program and packaging labeling requirements.

Chinese standards for single-use medical rubber gloves are: GB 10213-2006 *Single-use Medical Rubber Inspection Gloves*, GB 7543-2006 *Single-use Sterile Rubber Surgical Gloves*, GB/T 24787-2009 *Single-use Non-sterile Rubber Surgical Gloves*. In Europe, single-use medical rubber gloves shall comply with EU standards EN 455-1, EN 455-2, EN 455-3 and EN 455-4.

Chinese current national standards GB 10213-2006 (equivalent to ISO

11193.1-2002) and GB 7543-2006 (equivalent to ISO 10282:2004) are in line with ISO standards. GB/T 24787-2009 is a standard independently formulated by China. The comparison between the technical level of the three standards and between GB and the EU standards EN 455-1, EN 455-2, EN 455-3 and EN 455-4 is listed in table 3-1.

Table 3-1 Comparison of Chinese and European Standards for Single-use Medical Rubber Gloves

	China		EU Standards				Analysis and Specification
Standard number and name	GB 10213-2006 Single-use medical rubber examination gloves (IDT ISO 11193.1: 2002)	GB 7543-2006 Single-use sterile rubber surgical gloves (IDT ISO 10282:2014)	EN 455-1: 2000 Medical gloves for single use- Part 1: Requirements and testing for freedom from holes	EN 455-2: 2015 Medical gloves for single use- Part 2: Requirements and testing for physical properties	EN 455-3: 2015 Medical Gloves for Single Use - Part 3: Requirements and Testing for Biological Evaluation	EN 455-4: 2009 Medical gloves for single use- part 4: Requirements and testing for shelf life determination	EU standards can be divided into 4 parts according to different requirements for gloves: water impermeability, physical properties, biological evaluation and storage requirements
Classification	Type 1: Made from natural rubber latex Type 2: Made from synthetic rubber latex	Type 1: Made from natural rubber latex Type 2: Made from synthetic rubber latex	——	——	——	——	Not classified by EU standards
Material	Compounded rubber: natural rubber, nitrile rubber, neoprene rubber, styrene-butadiene rubber, iso-amyl rubber, styrene rubber, thermoplastic elastomer solution, or	Compounded rubber: natural rubber, nitrile rubber, neoprene rubber, styrene-butadiene rubber, iso-amyl rubber, styrene rubber, thermoplastic elastomer solution, or	——	——	——	——	The main material of glove is not given clearly, but it is reflected in the tensile property requirement of physical properties

	styrene-biphenyl rubber. For ease of wear, a lubricant, powder, or polymer coating complying to ISO 10993 can be used for surface treatment. Any paint used should be non-toxic. The transportable substance used for surface treatment shall be bioabsorbable. Gloves provided to users shall comply with the requirements of the relevant part of ISO 10993. Where necessary, the manufacturer shall make it easy for the purchaser to obtain information that meets these requirements	styrene-biphenyl rubber.					
Water-tightness	Water-tightness	Water-tightness	Water-tightness	____	____	____	
Sterilization	If sterilization is needed, the types of glove sterilization treatment shall be marked as required.	If sterilization is needed, the types of glove sterilization treatment shall be marked as required.	____	____	____	____	EU sterilization test shall be carried out in accordance with the sterilization method specified in EN ISO 11607.

Tensile properties	Breaking force before aging: ≥7.0N	Breaking force before aging: Type 1≥12.5N; Type 2≥9.1N Fixed extension load 300% before aging: Type 1≥2.0N; Type 2≥3.0N	——	Surgical gloves: ⩾9.0N Examination / procedure ⩾6.0N (non-plastic materials such as PVC, PE), ⩾3.6N (plastic (Such as PVC, PE).	——	——	70 ℃ × 7 days before and after aging with the same performance.
	Elongation at break before aging: Type 1 ≥650%, Type 2 ≥500%	Elongation at break before aging: Type 1 ≥700%, Type 2 ≥600%					Because the minimum thickness of gloves is not specified in EU standards, and the types of cutters used in the test are different, the width of the test specimen is 3mm.

							Therefore, it is no comparable regarding this performance.
	Breaking force after aging: Type 1 ≥6.0N; Type 2 ≥7.0N Elongation at break after aging: Type 1 ≥500%; Type 2 ≥400%	Breaking force after aging: Type 1 ≥9.5N; Type 2 ≥9.0N Elongation at break after aging: Type 1 ≥550%; Type 2 ≥500%					
Limit of powder residue	Not specified	Not specified			≤2.0mg		GB 24788-2009 has same corresponding requirements.
Chemicals					The content of chemicals used shall not exceed the limit specified in ISO 10993-2017, and as small as possible, the chemicals used		The regulations in GB standards compliance with all requirements specified in ISO 10993.

					shall not affect the user's health.		
Endotoxicity					⩽20 each glove		The requirements in the GB standard meet all the requirements of ISO 10993.
Water extraction protein					The minimum water extraction protein content shall be indicated.		In GB 24788-2009 it is required that this value shall be not exceed 200 μg/ dm2. However, there is no maximum limit in EU standards.
Shelf life						For any new product or change, the product should be tested for shelf life.	

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.