Disclaimer

The analyses offered in the annexes below provide a technical comparison between relevant Chinese and European standards in the fight against the COVID-19 pandemic. They constitute a purely academic exercise, offering a text comparison of technical information provided by the relevant Technical Committees of CEN and CENELEC, based in part on information provided by the Standardization Administration of China (SAC).

As such, the information below cannot be attributed any legal value, nor can it be used as a legal basis for putting products complying with these Chinese standards on the European market.

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Annex I Comparison of Standards of Surgical Masks

1. EN 14683-2019 Versus YY0469-2011 Comparative analyses

Surgical masks are mainly used in the operating room or other similar medical environment. The focus is to is to protect a patient or an aseptic environment and in certain cases also protect the wearer from splashes generated during treatment of the patient. As such surgical masks prevent the possible spatter of blood, fluid through the mask to contaminate the wearer. The key core indicators are generally filtration efficiency, blood penetration, microorganisms, pressure difference, bioburden, etc.

Surgical masks in China shall comply with YY0469 standard, and the surgical masks in EU shall comply with EN14683: 2019 standard:

- For **particle filtration efficiency**, YY 0469-2011 stipulates particle filtration rate (PFE) ≥ 30%, while EN14683-2019 has no requirement;
- For **bacterial filtration efficiency**, YY 0469-2011 stipulates that bacterial filtration efficiency (BFE) ≥95%, while in EN14683-2019 there're three classes: Type I:≥95%, Type II and Type IIR:≥98%;
- For **blood penetrability**, the requirement in YY 0469-2011 ≥16kPa, while EN14683-2019 only requires Type IIR, with the index ≥16kPa.

Comparison of key requirements between two standards is listed in Table 1-1.

Table 1-1 Comparison of key requirements between two standards

Country	China	European Union
Product	surgical masks	surgical masks
Standard	YY0469-2011 Surgical Masks	EN 14683-2019 Surgical Masks-Requirements and Test Methods
Scope	Suitable for disposable masks worn by clinical medical personnel during invasive operation	Suitable for use in surgery or other similar medical environment to limit the spread of pollutants produced by other workers to patients, and to

		effectively block the discharge of pollutants from the mouth and nose of suspected carriers or patients with clinical symptoms.
Tightness	X	X
Particle Filtration Efficiency (PFE)	≧30%	X
Bacterial Filtration Efficiency (BFE）	≧95%	Type I:≥95% Type II、Type IIR:≥98%
Pressure Difference	√（≤49Pa）	Type I and Type II：≤40Pa Type IIR: ≤60Pa（kPa）√
Blood Penetration	√（≥16kPa）	Type I and Type II：X Type IIR: ≥16（kPa）√
Surface Moisture Resistance	X	X
Microbiological Index	√	√
Flammability	√（The masks should burn no more than 5 S after leaving the flame）	X
Exhalation Value	X	X
Marking	Standard number, product name, production date and batch number, manufacturer's name and contact information, product registration certificate number, instructions for use, words and symbols of "disposable use". If the product is sterilized, the	Standard number and mask type（Type I, Type II or Type IIR）

	corresponding sterilization mark shall be provided, indicating the sterilization method and the sterilization period. Specification, size and tolerance. And product use.	

Note: the comparison provided is only a text comparison of technical information and cannot be attributed any legal basis for choosing to put products on the EU market.

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Annex II Comparison of the test Standards of filter protection masks for single use

1. EN 149-2001 Versus GB 2626-2006

Motivation

Due to the worldwide pandemic of the SARS-CoV-2 virus and the resulting disease, COVID-19, the available and deliverable stock of the above-mentioned protective masks with the European standard EN 149-2001 (FFP2 - Filtering Face Piece 2) is dropped to a very critical level.
This situation will be further aggravated in the near future by the expected increase in the number of cases and, in particular, in the number of patients requiring inpatient treatment and possibly transfer.
There are already dubious suppliers on the market who offer to supply appropriate masks against a 100% down payment. A reliable delivery should not be expected!
Other suppliers offer to add a mask type according to Chinese test standard to their stocks in order to be able to continue to meet the needs.

Question

To what extent are the worldwide national test standards, in particular the standard GB2626-2006 (KN95) from the Chinese area comparable with the European standard applied in the Federal Republic of Germany?

Current status

According to a Technical Bulletin from 3M with status 01/2020, Rev. 2, the following standards are approximately equal to each other:

- **N95 (United States NIOSH-42CFR84)**
- **FFP2 (Europe EN 149-2001)**
- **KN95 (China GB2626-2006)**
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018)

Based on the above-mentioned question, only the following test standards will be compared in the following:

1. EN 149-2001(European) and
2. KN95 (Chinese)

Both standards describe different filter classes:

EN 149-2001

- FFP1 (filter performance for the prescribed test media min. 80%)
- **FFP2 (filter performance for the prescribed test media min. 94%)**
- FFP3 (filter performance for the prescribed test media min. 99%)

All mask classes are tested with both an oil-based and a water-based aerosol.

GB2626-2006:

- KN90 (Filter capacity for the prescribed test medium min. 90%)
- **KN95 (Filter capacity for the prescribed test medium min. 95%)**
- KN100 (Filter capacity for the prescribed test medium min. 99.97%)
- KP90 (Filter capacity for the prescribed test medium min. 90%)
- KP95 (Filter capacity for the prescribed test medium min. 95%)
- KP100 (Filter capacity for the prescribed test medium min. 99.97%)

KP: Test medium is a paraffin-containing mist - oil-borne
KN: Test medium is a NaCl aerosol - water borne

In the following, the filter classes FFP2 and KN95 will be compared with each other according to the current needs and questions.

	FFP2 (EN 149-2001)	**KN95 (GB2626-2006)**	**Notes**
Filter capacity / filter performance	min. 94%	min. 95%	GB2626 is better
Test substrate solution	NaCl + paraffin oil	NaCl	FFP2 additionally oil-borne test substrate solution, but irrelevant in the present case
Volume flow rate	95 L/min	85 L/min	
Internal leakage	max. 8%	max. 8%	same requirement
Inhalation resistance	max. 70 Pa at 30l/min max. 240 Pa at 95l/min max. 500 Pa when added	max. 350 Pa at 160l/min	Testing at EN 149-2001 with different flow rates, in GB2626 only with one.
Expiration resistance	max. 300 Pa at 160l/min	max. 250 Pa at 85l/min	
Requirements for	No information	Pressure relief to 0	

the exhalation valve		Pa in min. 20s	
Necessary effort	No information	1180 Pa	

Specifications in the EN 149 to filter not only non-oily particles but also particles containing oil are in GB2626-2006 not required. The filter performance of the filter according to GB2626-2006 is therefore not tested for oily aerosols and therefore not yet proven.
The filter performance of the masks for non-oily particles produced according to the Chinese standard is minimal better than the European standard.

A requirement for the filtering of oily particles (paraffin mist) is for the current application requirement (SARS-CoV-2) not detectable. However, it must be ensured during procurement that these masks are not subsequently used for PPE equipment.

Masks with an exhalation valve may only be used for the protection of personnel!

The maximum breathing resistances are regulated differently in the standards. In the present application case these are not relevant.
The US American Center for Disease Control and Prevention (CDC) presents the two compared standards with regard to protection factor to one level, see: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternatestrategies.html

Conclusion

The masks of the standards EN 149-2001 (FFP2) and GB 2626-2006 (KN95) are well comparable for the present case (SARS-CoV-2). The aerosol in question (SARS-CoV-2) is not oil-bound.
The filter performance of GB 2626-2006 is slightly better.
The leakage tolerance is identical in both standards.
It must be ensured that the GB2626-2006 standard is observed and that no counterfeit products are used.

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Annex III Comparison of Single-use Medical Rubber Gloves Standards

1. EN 455-1, EN 455-2, EN 455-3, EN 455-4 Versus GB 10213-2006, GB 7543-2006

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 1: Made from natural rubber latex	——	a) Requirements for all surgical gloves. b) Requirements for all examination	——	——	EU differentiation by indend use (surgical or examination) and material (NR latex/synthetic and thermoplastics)

				gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene). c) Requirements for examination gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			
	Type 2: Made from synthetic rubber latex	Type 2: Made from synthetic rubber latex					

Material	Compounded rubber: natural rubber, nitrile rubber, neoprene rubber, styrene-butadiene rubber, iso-amyl rubber, styrene rubber, thermoplastic elastomer solution, or styrene-biphenyl rubber. For ease of wear, a lubricant, powder, or polymer coating complying to ISO 10993 can be used for surface treatment.	Compounded rubber: natural rubber, nitrile rubber, neoprene rubber, styrene-butadiene rubber, iso-amyl rubber, styrene rubber, thermoplastic elastomer solution, or styrene-biphenyl rubber.	——	See row above (Classification)	—— Gloves shall not be dressed with talcum powder (magnesium silicate). Chemicals known to be allergenic shall be avoided if technical alternatives exist. Wherever possible allowable limits for	——	The main material of glove is not given clearly, but it is reflected in the tensile property requirement of physical properties

				leachable residual chemicals shall be established using EN ISO 10993-17 and these limits shall be complied with. Wherever this is not possible, the residual chemicals level shall be "As Low As Reasonably Practicable" (ALARP – see EN ISO 14971)			
	Any paint used should be non-toxic. The transportable substance used for surface treatment shall be bioabsorbable.			The manufacturer shall disclose, upon request, a list of chemical			

				ingredients either added during manufacturing or already known to be present in the product such as accelerators, antioxidants and biocides, that are known to cause adverse health effects based on current data. Medical gloves for single use shall be evaluated as described in the EN ISO		
	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					

					10993 series.		
Water-tightness	Water-tightness	Water-tightness	(Water-tightness) Medical gloves for single use shall not leak when tested in accordance with water tightness test for detection of holes	——	——	——	
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 ISO. 11737. EU labelling requirements for sterilization method

							are specified in EN ISO 15223-1.
Tensile properties	Breaking force before aging: ≥7.0N	Breaking force before aging: Type 1≥12.5N； Type 2≥9.1N	——	Surgical gloves: Force at break ≥9.0N Examination / procedure gloves: Force at break ≥6.0N all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchlori	——	——	70 ℃ × 7 days before and after aging with the same performance.

				de, polyethylene) Force at break ≥3.6N gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			
		Fixed extension load 300% before aging：Type 1≥2.0N; Type 2≥3.0N					
	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	Breaking force after aging: Type 1 ≥9.5N; Type 2 ≥9.0N				Surgical gloves: Force at break ≥9.0N Examination / procedure gloves: Force at break ≥6.0N all examination gloves, except gloves made from thermoplastic materials (e.g.	Medical gloves shall comply with the requirements of the EN 455 series of standards until the end of their stated shelf life

	Elongation at break after aging: Type 1 ≥500%; Type 2 ≥400%	Elongation at break after aging: Type 1 ≥550%; Type 2 ≥500%				polyvinylchloride, polyethylene). Force at break ≥3.6N gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).	
Limit of powder residue	Not specified	Not specified			For powder free gloves the total quantity of powder residues determined according to the test method under		GB 24788-2009 has same corresponding requirements.

					5.2 shall not exceed 2 mg per glove. Any glove containing more than 2 mg powder is a powdered glove.		
Chemicals					(The content of chemicals used shall not exceed the limit specified in ISO 10993-2017, and as small as possible, the chemicals used shall not affect the user's health.) Chemicals		The regulations in GB standards compliance with all requirements specified in ISO 10993.

					known to be allergenic shall be avoided if technical alternatives exist. Wherever possible allowable limits for leachable residual chemicals shall be established using EN ISO 10993-17 and these limits shall be complied with. Wherever this is not possible, the residual chemicals level shall be "As Low As Reasonably		

					Practicable" (ALARP – see EN ISO 14971).		
Endotoxicity					The manufacturer shall monitor the endotoxin contamination of sterile gloves using the test method specified in 5.1 if the gloves are labelled with 'low endotoxin content'. For such labelled gloves the endotoxin content shall not		The requirements in the GB standard meet all the requirements of ISO 10993.

					exceed the limit of 20 endotoxin units per pair of gloves.		
Water extraction protein					(The minimum water extraction protein content shall be indicated.) The manufacturer shall monitor the process limit of leachable protein in the finished gloves containing natural rubber latex. The leachable protein level shall be "As		In GB 24788-2009 it is required that this value shall be not exceed 200 μg/ dm^2. However, there is no maximum limit in EU standards.

					Low As Reasonably Practicable" (ALARP).		
Shelf life						(For any new product or change, the product should be tested for shelf life.) Before a new or significantly modified product is placed on the market this European Standard requires: - a completed real time study to determine	

						shelf life or - a real time study to determine shelf life shall have commenced and an accelerated ageing study shall have been completed.	

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Annex IV Comparison of Medical Protective Clothing Standards

1. EN 14126:2003 + AC 2004 Versus GB 19082-2009

EN 14126:2003 + AC 2004 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents	**GB 19082-2009** Technical requirements for single-use protective clothing for medical use
Explanation: It is easy to o see that some essential requirements are congruent. (resistance to penetration of synthetic blood), but that in other requirements, either there is no congruence, or no statement is made about some properties. My impression here is that the Chinese standard is more likely to be intended for medical personnel, as it refers to bacteriological properties and the possibility of sterilization. The EN 14126 suit is rather designed for laboratories or pharmaceutical production and not for hospitals (the scope excludes medical use). Therefore a statement is difficult to make. The mechanical properties with 45 N for tensile strength and an extensibility of 15 % seem to be reasonable, not worse than in EN 14126, which does not provide a minimum value, however, but only the classification into classes according to EN 14325.	A clear statement is not possible, the GB 19082 has some feasible aspects, the scope for use seems to be different, and so it is not possible to give a good estimation. It would be better to compare, what was used in Europe in the past, verifying haptic and design and strength, and if it is certified with GB 19082 and gives an impression, that it looks like and haptic feels like, what was in use before, then I would give it a try. That would be better, then to use none.

Note: the comparison provided is only a text comparison of technical information and cannot be attributed any legal basis for choosing to put products on the EU market.

Annex V Comparison of Personal Protective Equipment Standards

1. EN 14605:2009 + A1:2009 Versus GB 24539-2009

EN 14605:2009 + A1:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only	**GB 24539-2009** Protective clothing. Performance requirements of chemical protective clothing.
<u>Explantation:</u> Scope: GB 24539 vs EN 14605 seems to be the same Type: OK, Type 3a seems to be similar to Type 3 Type 3b seems to be similar to Type 4 Partial Body not known. Abrasion resistance: The Chinese requirement is stronger as for Type 3 Chemical Resistance: The Chinese requirement is stronger as for Type 3 Same as for Type 4	**GB 24539** has clearer defined requirements for protective clothing against liquid chemicals, especially for type 3 and 4. However, partial body protection is not defined. Both standards can be used in the market.

Note: the comparison provided is only a text comparison of technical information and cannot be attributed any legal basis for choosing to put products on the EU market.

2. EN ISO 13982-1:2004/Amd 1:2010 Versus GB 24539-2009 and GB/T 29511-2013

EN ISO 13982-1:2004/Amd 1:2010 Protective clothing for use against solid particulates — Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing) — Amendment 1	GB 24539-2009 Protective clothing. Performance requirements of chemical protective clothing GB/T 29511-2013 Protective clothing. Chemical protective clothing against solid particulates.
<u>Explanation</u> Scope: GB 24539/GB/T and 29511-2013 vs EN ISO 13982:2004 +Amd1 2010 seems to be OK, Type: OK, Type 4 seems to be similar to Type 5 Partial Body not known. Abrasion resistance: same levels acceptable Chemical Resistance: same levels acceptable Cold Flex -30°C : no req for China, but this req is rarely needed for the use cases we are talking about with SARS-Cov2; other mech. req. are similar Total Inward Leakage or Filtration efficiency, seems to be better for the Chinese standard suit. They also defined a hydrostatic pressure test for this kind of suit, which is in my point of view good	We find better defined requirement type 5 clothing, more stringent, due to the abrasion and hydro pressure test that needs to be fulfilled.

Note: the comparison provided is only a text comparison of technical information and cannot be attributed any legal basis for choosing to put products on the EU market.

Annex VI Comparison of Personal Eye Protector Standards

1. EN 166:2001 Versus GB 14866-2006.

Personal eye protectors include various forms and functions of eye and face protection equipment used by personnel in various environments and occupations. The product form and structure mainly include glasses, eye goggles, face shield, etc. In the context of epidemic prevention and control, the product structure forms used are mainly eye goggles and face shields. In China and in Europe, the technical requirements for personal eye protection are mainly composed of two categories of requirements: basic requirements and optional rquirements.

The basic requirements mainly include: visible light transmittance and impact resistance. Optional items include high-speed particle impact resistance, etc. Among them, the chemical droplet protection performanceis mainly related to the epidemic control, which is called protection against droplets and splashes in the European standard.

For **visible light transmittance**, the visible light transmittance of GB 14866-2006 for colorless and transparent lenses should be> 0.89, EN 166 requires for lenses that only provide mechanical or chemical protection, the visible transmittance > 0.744.

For **impact resistance**, GB 14866-2006 requires that lenses and eye protector can withstand the impact of steel balls with a diameter of 22mm and 45g falling from a height of 1.3m without being damaged.

For **protection against droplets and splashes of liquids**: GB 14866-2006 and EN 166-2001 both require the use of a liquid spray for coloration testing, which requires no staining in the center of the covered area of the eye protector. The EN standard only tests eye goggles, and the coverage of the face shield is evaluated.

Comparison of key requirements from two standards is listed in table 6-1.

Table 6-1 Comparison of Key Requirements of Personal Eye Protection between Two Standards

Country	China	European Union	CEN/TC 85 remarks
Product	Personal eye-protector: eye goggles, face shields	Personal eye-protector: eye goggles, face shields	ok
Standard	GB 14866-2006 The specifications for personal eye-protectors	EN 166:2001 Personal eye-protection — Specifications	ok
Scope	All kinds of personal eye protectors except those providing protection against nuclear radiation, X-ray, laser, ultraviolet, infrared and other radiation.	Various types of personal eye protection, including eye protection that provides mechanical, optical, and droplet protection.	ok
Refractive powers	Lens : optical class 1	Lens : Optical class 1, 2 and 3	Ok
Visible light transmittance	for colorless and transparent lenses: > 0.89	for lenses that only provide mechanical or chemical protection: > 0.744	>74.44 % ok
Scattering light	Missing	< 1.00 cd/(m².lx)	Nok
Impact resistance	Requires that lenses and eye protector can withstand the impact of steel balls with a	Requires that lenses and eye protector can withstand the impact of steel balls with a	Ok. Note: EN 166 allows a minimum robustness (static deformation not

	diameter of 22mm and 45g falling from a height of 1.3m without being damaged.	diameter of 22mm and 45g falling from a height of 1.3m without being damaged.	impact)
Stability at an elevate temperature / heat resistance	67°C during 3 min following by immersion in cold water (< 4°C) following by optical powers checking	EN 168: 55°C during 1 hour	Nok
UV resistance	Missing	1/ Visible transmittance change within tolerances 2/ Scattering light after UV radiation < 1.00 cd/(m².lx)	Nok
Resistance to ignition	Missing	No combustion after withdrawal of hot steel rod (650°C)	Nok
Protection against droplets and splashes of liquids	Require the use of a liquid spray for coloration testing, which requires no staining in the center of the covered area of the eye protector.The GB standard tests both eye goggles and the face shields.	Require the use of a liquid spray for coloration testing, which requires no staining in the center of the covered area of the eye protector. The EN standard only tests eye goggles, and the coverage of the face shield is evaluated.	EN 168 specifies for face shield a minimum heigth of 150 mm

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