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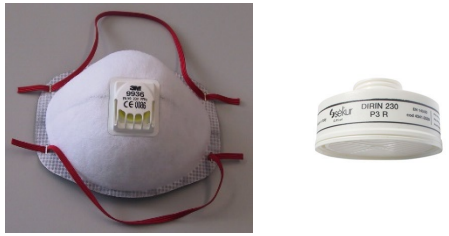
7 April 2020

Protection masks

Types of protection masks

Protective effect	low → high		
	Face masks	**FFP masks**	**Particle filter**
Test standard	DIN EN 14683	DIN EN 149	DIN EN 143
Recommendation for	Population during a pandemic	Medical staff during a pandemic	Workers with close contact with hazardous substances (independent of time)
Primary protection	Stop spreading of pandemic	Individual protection	Individual protection
Strategy	Individual/collective	individual	individual
Examples			

Standard for protection masks

Mask type	Standard	Filtration effect/ mask categories		
Face masks	Europe: EN 14683	Type I	Type II	Type III R
		BFE: > 95%	BFE:> 98%	BFE: >98%
		PFE: -	PFE: -	PFE: -
	USA: ASTM F2100	Level 1	Level 2	Level 3
		BFE: > 95%	BFE: > 98%	BFE: >98%
		PFE: > 95%	PFE: > 98%	PFE: > 98%
	China: YY 0469	BFE: > 95% PFE: -		
FFP masks	Europe: EN 149:2001	FFP1	FFP2	FFP3
		0,6 µm > 80%	0,6 µm > 95%	0,6 µm > 95%
	USA: NIOSH (42 CFR 84)	N95	N99	N100
		0,3 µm > 95%	0,3 µm > 99%	0,3 µm > 99,7%
	China: GB2626	KN95	KN99	KN100
		0,3 µm > 95%	0,3 µm > 99%	0,3 µm > 99,7%

BFE: bacterial filtration effect

PFE: particle filtration effect

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General structure

- **Mostly 3 layers:**

Inner layer: liquid absorbing non-woven, skin friendly, allergy-free

Filter medium: microfibre non-woven produced by meltblown process

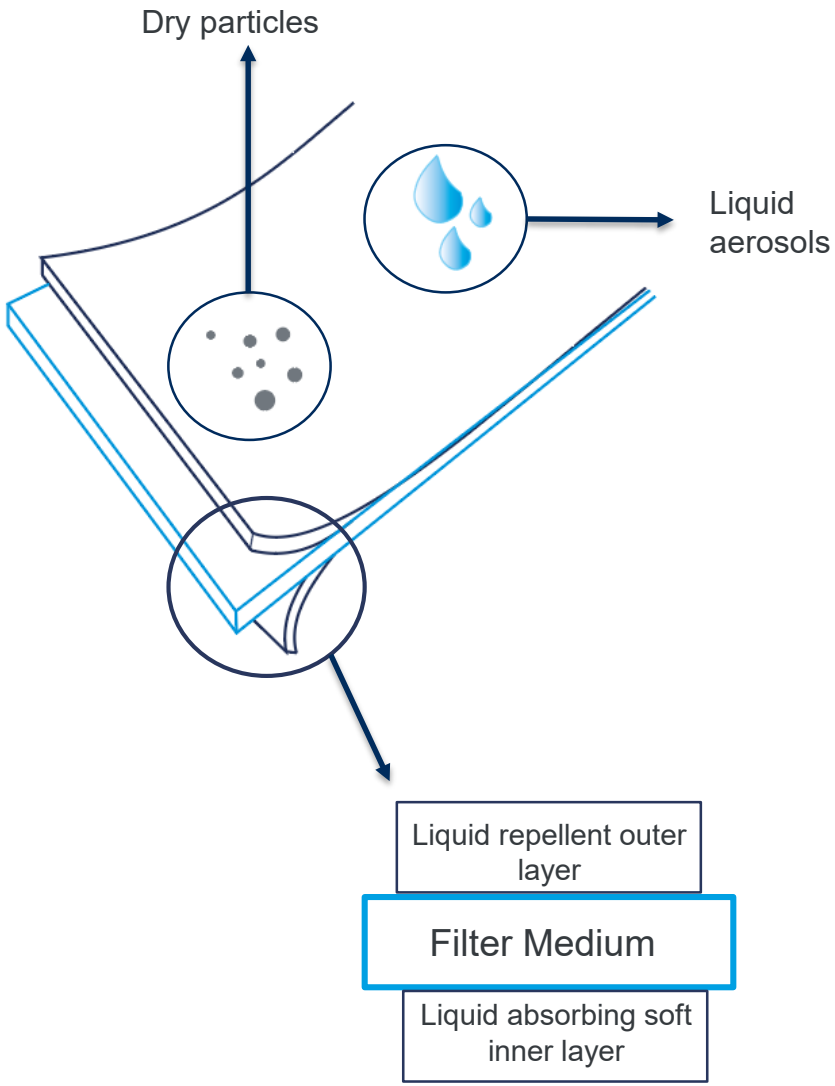
Outer layer: liquid repellent non-woven

- **Sometimes 4 layers:**

➢ additional filter layer out of activated carbon

➢ 2 liquid repellent outer layer

- **Most common material:** Polypropylen (PP)



Face-masks (surgical masks)

- Thin masks
- Structure: filter layer that is embedded in 2 fabric layers
- To prevent spread of fluids from mask wearer
- Face masks do not fit tightly and therefore do not protect the wearer against airbone infection
- Help to avoid contact with contaminated hands

Standard face mask - EN 14683

test	Type I	Type I R	Type II	Type II R
Bacterial filtration effect	>95%	>95%	>98%	>98%
Breathing resistance/ Pressure difference Pa	<29,4	<49,0	<29,4	<49,0
Splash resistance s mm Hg	-	>120	-	>120
Resistance against liquid splashes/ spray water	-	yes	-	yes

Fluid-resistant masks are available both as surgical and examination masks. Type IR and Type IIR masks meet or exceed the spray resistance of 120 mmHG specified in the EN standard

FFP-masks

- Particle filter half mask (filtering face piece, FFP)
- Protection against solid and liquid aerosols
- 3 categories: FFP1, FFP 2, FFP3
- From FFP2 onwards there is protection against "substances which are carcinogenic, mutagenic or toxic to reproduction", and also against radioactive substances and "airborne biological agents classified in risk group III
- Tight-fitting FFP2 masks provide adequate protection against infectious aerosols, including viruses

Standard FFP-mask: DIN EN 149 (1/3)

Tests:

1. Total inward leakage
2. Filter penetration
3. Breathing resistance
4. Flammability
5. Skin compatibility
6. Function of exhalation valve
7. Resistance against detergents and disinfectants (only if reusable)

Standard FFP-mask: DIN EN 149 (2/3)

1. Total inward leakage:

Ten test persons wearing a respirator perform a series of exercises on a treadmill. They measure the amount of test aerosol that enters the respirator through the filter, sealing lip and, if necessary, the valve. In the FFP2 category, the leakage must not exceed 8 % in eight out of ten test results.

2. Filter penetration:

The filtering effect of twelve respirators is tested with a sodium chloride aerosol and a paraffin oil mist.

3. Breathing resistance:

The breathing resistance generated by the filter of the respirator is measured at an air flow of 30 l/min and 95 l/min.

4. Flammability:

Four breathing masks are passed through a flame of 800 (±50) °C at a speed of 5 cm/s. The respirator must not burn after being removed from the flame.

5. Skin compatibility:

The materials which may come into contact with the skin of the wearer must not have an irritant effect or any other negative effect on health.

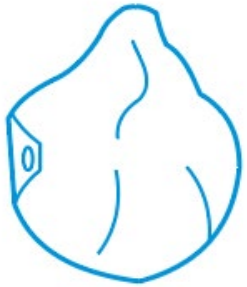
6. Resistance against detergents and disinfectants:

If the particulate filter half mask is intended to be reusable, the materials must be resistant to the detergents and disinfectants.

Standard FFP-mask: DIN EN 149 (3/3)

Categorie	Results		
	FFP1	FFP2	FFP3
Max. total leakage	22%	8%	2%
Max. filter penetration	20%	6%	1%
Max. breathing resistance 30 l/min	0,6 mbar	0,7 mbar	1,0 mbar
Max. breathing resistance 95 l/min	2,1 mbar	2,4 mbar	3,0 mbar
Filter performance	Min. 80%	Min. 94%	Min. 99%

Protection masks



	Face mask	FFP2/FFP3 mask without valve	FFP2/FFP3 mask with valve
Protects wearer	No	Yes	Yes
Protects environment	Yes	Yes	No
Standard	EN 14683	EN 149 (EN 14683)	EN 149

UNIDYNE for protection masks

UNIDYNE	performance tests				toxicological information				
	water repellency	water column	alcohol repellency	other	Acute toxicitiy Oral LD50 >2000 mg/kg (Rat)	No primary irritant effect/ skin corrosion (OECD 404)	No sensitizing effect on respiratory or skin (OECD 429)	Germ cell mutagenicity: negative (Ames Assay)	ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
TG-5506	✓	✓	✓	antistatic on PP high temp. Stability	✓*	✓*	✓*	✓*	**
TG-5601	✓	✓	✓	excellent performance on PES and PES blends	✓	✓	✓	✓	**

* Result is based on data obtained from a product of similar composition

** test results follow

Please note:
It is necessary to test the finished end product according to the toxicological requirements for the medical sector.

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ISO 10993

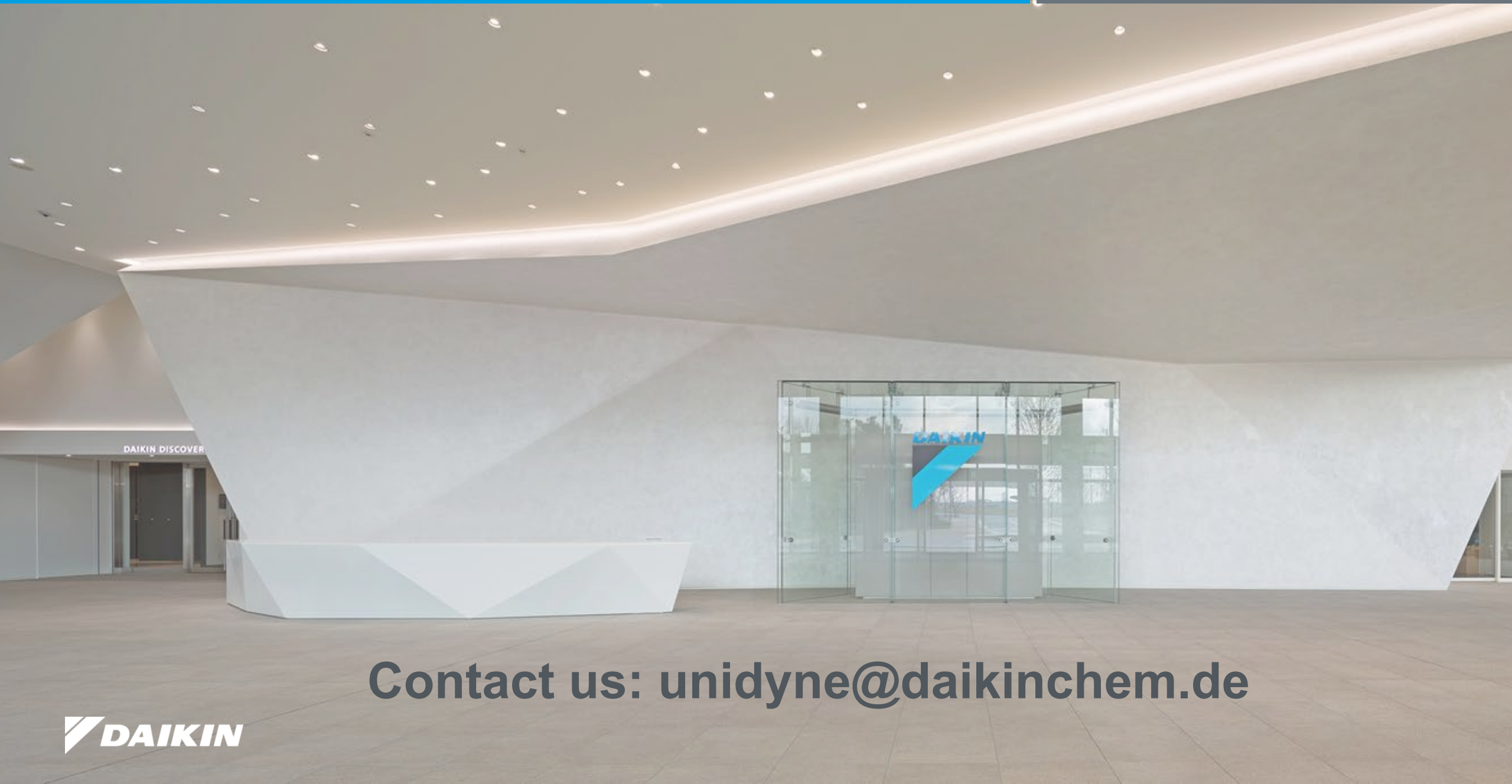
The ISO 10993 standard is a series of ISO standards for the biological assessment of medical devices. The standard is particularly relevant for manufacturers of medical devices and test laboratories. The aim of the standard is to assess the biological assessment of the compatibility of the materials used with the body. Not only products but also raw materials for the manufacture of medical devices are examined. The series of standards is not limited to implantable medical devices, but concerns a large number of medical devices. In addition to the biological test, the standard also includes physico-chemical tests and analyzes of dissolved substances and substances and stipulates compliance with limit values for substances that can be extracted.

ISO 10933 has several standards (ISO 10933-1 until ISO 10933-22)

→ **ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity**

ISO 10993-5

Medical device categorization by			Biological Effect												
Nature of Body Contact		Contact Duration A-limited (≤24 h) B-prolonged (>24 h to 30 d) C-permanent (> 30 d)	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity	Degradation
Category	Contact														
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O			
	Breached or compromised surface	A	X	X	X	O	O								
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O	O		
External communicating device	Blood path, indirect	A	X	X	X	X	O					X			
		B	X	X	X	X	O	O				X			
		C	X	X	O	X	O	X	X	O	X	O	O		
	Tissue/bone/ dentin	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Circulating blood	A	X	X	X	X	O		O		X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		
Implant device	Tissue/bone	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Blood	A	X	X	X	X	O		O	X	X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		
X = ISO 10993-1:2009 recommended endpoints for consideration															
O = Additiona+A9:P35l FDA recommended endpoints for consideration															



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