Townhall: Information on Medical Face Masks, Face Filtering Respirators and Face Shields

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Topics:

- Technical specification:
  1. Medical Face Masks
  2. Respirators
  3. Face Shields
- Main standards that ensure technical performance
- Reference documents to help choose and evaluate suppliers

1. Medical Face Masks

- Typically 3 layers of nonwoven material
  1. Outer layer for strength: spunbond, thicker fibers and melted in a consistent pattern
  2. Middle layers, meltblown, finer fibers, lofty material to filter droplets
  3. Inner layer, may be spunbond, cellulose

- Standards: ASTM F2100, EN 14683, YY 0469/0969
- Tested for filtration (bacterial droplets or sub-micron particles)
- Breathability, as pressure drop (Pa/cm^2)
- Fluid resistance (synthetic blood penetration, visual pass/fail test) @ 80, 120 or 160 mmHg
- Other tests:
  - Flammability (American standard)
  - Microbial cleanliness (European standard)

1. Medical Face masks:
ASTM F2100 performance levels

TABLE 1 Medical Face Mask Material Requirements by Performance Level

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	<4.0	<5.0	<5.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

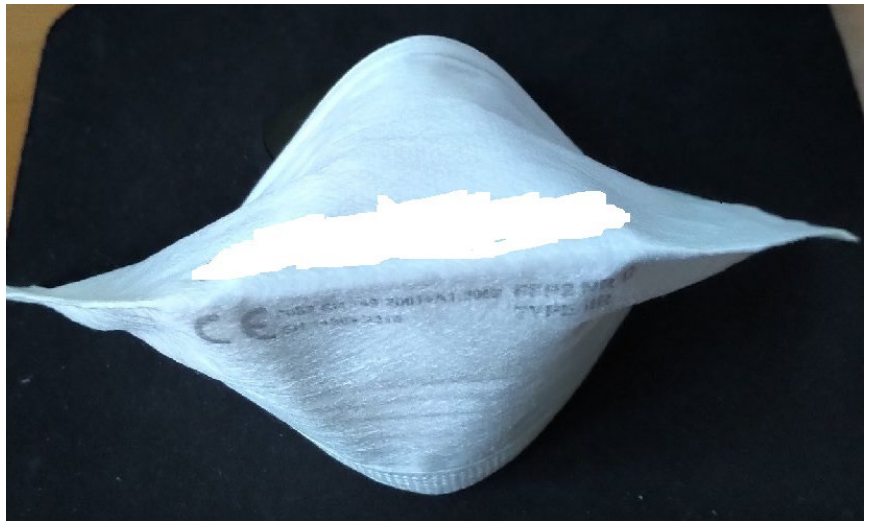
1. Medical Face masks:
EN 14683 performance levels

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

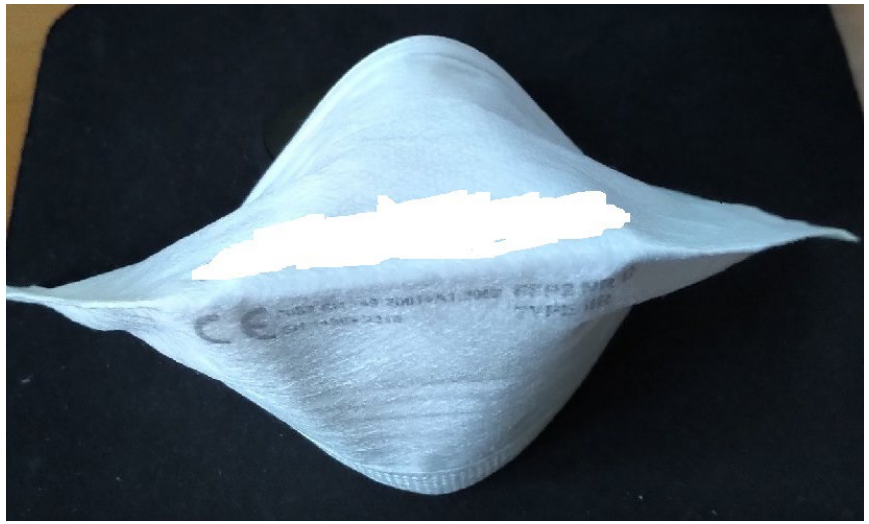
[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

2. Face Filtering Respirators (FFR): N95 (N99, Surgical N95), FFP2 (FFP3)



- Multiple layers of nonwoven material,
- Valve or no valve
- Multiple shapes designed to minimize gaps in seal around the face
- Standards: NIOSH 42 CFR Part 84, EN 149 “FFP2”, GB 2626
- Tested for filtration (NaCl) ~95%, at 85 or 95 L/min
- Breathability, as max allowable breathing resistance, at inhalation and exhalation (Pa or mbar)

2. Face filtering Respirators (FFR): N95, FFP2



- **<u>FIT</u>**
  - EU: tested for a sample of 10 human participants
  - US: fitted to wearer, using a range of sizes and a qualitative fit test
- "Surgical N95" or FFP2+EN 14683 ensure the respirator is fluid resistant (Synthetic Blood Penetration)
- Other tests:
  - CO2 clearance, not more than 1% trapped in the respirator
  - Compatibility with skin
  - Flammability (American standard)
  - Paraffin oil filtration (European standard)

3. Face shields:

- Clear plastic (polyester, acetate, mylar), many others for re-usable
- Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog resistant (preferable).
- Completely cover the sides and length of the face.
- May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.
- Standards: ANSI/ISEA Z 87.1, EN 166 (for re-usable)

Disease Commodity Package for COVID-19

World Health Organization

COVID-19 v5

Operational Support & Logistics
Disease Commodity Packages

Agent's Biosafety Level (to be confirmed): BSL2, Virus culture BSL3

Related links: COVID-19 [LINK]

Epidemic Potential: Under investigation

Last Update: 29 April 2020

Managing Epidemics Handbook [LINK]

SURVEILLANCE	Sample Collection	Diagnosis		
		Polymerase Chain Reaction (PCR)	Immunoassay	Culture
Laboratory confirmation of a COVID-19 case will trigger an thorough investigation. Because there currently is not a PCR test available testing may take several days or longer, WHO's recommended strategy is to begin an investigation immediately, thus requiring immediate operational support and supplies.	Upper and lower respiratory samples (nasopharyngeal and sputum samples)	No commercial rRT-PCR kits yet available; See interim nCoV laboratory guidance below	Not yet available	Viral transport medium

Note: Many diagnostics supplies are also used for **Case Management** purposes, but have been included only in **Surveillance**.

Laboratory testing for COVID-19 is in development

PREVENTION & CONTROL	Travel & Trade	Vaccine	Triage / Screening (PPE)
Based on current information it is assumed that COVID-19 is a zoonotic disease with human-to-human transmission occurring through droplets or contact. This human-to-human transmission may occur due to breaches in IPC practices. Thus, a central focus of any prevention/control strategy is protecting health care workers with appropriate IPC supplies and ensuring basic health logistics at responding facilities.	Animal source has not yet been identified	Several vaccine candidates for MERS-CoV are in development.	Standard precautions with an emphasis on hand and respiratory hygiene, plus additional precautions - specifically droplet and contact precautions. Airborne-related precautions are only required for aerosol-generating procedures. Personal protective equipment (PPE) for screening and for at-risk healthcare workers at healthcare facilities

Please see WHO technical guidance on IPC for COVID-19 [LINK]

R&D Blueprint [LINK]

CASE MANAGEMENT	Treatment			Personal Protective Equipment (PPE)
	Aetiological	Supportive		
There is no specific treatment or vaccine for COVID-19; however, R&D efforts for MERS-CoV are ongoing. See current WHO guidance on case management for MERS-CoV. WHO guidance on COVID-19 case management is in development.	Several candidates are under consideration for evaluation. On outbreak-specific basis, the Monitored Emergency Use of Unregistered Interventions (MEURI) may be considered. Please refer to most recent WHO guidance.	Oxygen Therapy with use of pulse oximeter highly recommended. Mechanical ventilation of severe cases (40%). Invasive ventilation and intensive care of critical cases.	Antibiotics, Pain/fever relief	PPE for at-risk healthcare workers at healthcare facilities. Respiratory (standard, droplet IPC); airborne-related precautions for aerosol-generating procedures. Possibly Home Care Kits for home isolation of asymptomatic or mildly symptomatic cases (in the case of a large outbreak).

https://www.who.int/emergencies/what-we-do/prevention-readiness/disease-commodity-packages/en/

Freely available standards

- ASTM: https://www.astm.org/COVID-19/
- EN: https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/
- ISO: https://www.iso.org/covid19