

मा. प्रधान सचिव सार्वजनिक आरोग्य विभाग यांनी निर्गमित केलेली अधिसूचना दि. ०३.०४.२०२० नुसार PPE KIT व N 95 Mask च्या दर्जा व गुणवत्ता प्रमाणीत करून घेण्यासाठी आवश्यक लागणारी नमुन्यासह कागदपत्रे.

अ.क्र	कागदपत्र
१	पुरवठादाराचे / उत्पादकाचा विनंती अर्ज.
२	उत्पादनाचे ३ नमुने
३	पुरवठादाराचा स्वतःचा (In-house) गुणवत्ता अहवाल.
४	नमुन्याचा मान्यताप्राप्त प्रयोगशाळेकडून अहवाल (NABL Report)
५	विविध गुणवत्ता प्रमाणपत्र.(प्रत्येक बाबीसाठी) e.g. SITRA/ DRDE, CE, ISO, ISI, NIOSH, EN, ASTM, wherever applicable
६	उत्पादक/ वितरक असल्याबाबतचे प्रमाणपत्र.
७	उत्पादन तयार करण्यासाठी लागणारे प्रमाणपत्र.
८	IEC प्रमाणपत्र, Bill of Entry

पत्ता

हाफकीन जीव औषध निर्माण महामंडळ, मर्यादित, (खरेदी कक्ष)
महाराष्ट्र शासनाचा अंगीकृत उपक्रम
आचार्य दौंदे मार्ग, परळ, मुंबई ४०० ०१२

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दू.क्र.:खरेदी कक्ष:- ०२२-२४१००४७८

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Check List

अ.क्र	कागदपत्र	जमा केले हो / नाही
१	पुरवठादाराचे / उत्पादकाचा विनंती अर्ज.	
२	उत्पादनाचे ३ नमुने	
३	पुरवठादाराचा स्वतःचा (In-house) गुणवत्ता अहवाल.	
४	नमुन्याचा मान्यताप्राप्त प्रयोगशाळेकडून अहवाल (NABL Report)	
५	विविध गुणवत्ता प्रमाणपत्र.(प्रत्येक बाबीसाठी) e.g. CE, ISO, ISI, NIOSH, EN, ASTM, wherever applicable	
६	उत्पादक/ वितरक असल्याबाबतचे प्रमाणपत्र.	
७	उत्पादन तयार करण्यासाठी लागणारे प्रमाणपत्र.	
८	IEC प्रमाणपत्र, Bill of Entry	

Personal Protection Equipment (PPE) - Specifications(for Contact & Airborne precautions)1. PPE Kit1.1 Gloves

- Nitrile
- Non-sterile
- Powder free
- Outer gloves preferably reach mid-forearm (minimum 280 mm total length)
- Different sizes (6.5 & 7)
- Quality compliant with the below standards, or equivalent:
 - a. EU standard directive 93/42/EEC Class I, EN 455.
 - b. EU standard directive 89/686/EEC Category III, EN 374
 - c. ANSI/SEA 105-2011
 - d. ASTM D6319-10

1.2 Coverall (medium and large)*

- Impermeable to blood and body fluids
- Single use
- Avoid culturally unacceptable colors e.g. black
- Light colors are preferable to better detect possible contamination
- Thumb/finger loops to anchor sleeves in place
- Quality compliant with following standard
 - a. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

1.3 Goggles

- With transparent glasses, zero power, well fitting, covered from all sides with elastic band/or adjustable holder.
- Good seal with the skin of the face
- ~~• Flexible frame to easily fit all face contours without too much pressure~~
- Covers the eyes and the surrounding areas and accommodates for prescription glasses
- Fog and scratch resistant
- Adjustable band to secure firmly so as not to become loose during clinical activity
- Indirect venting to reduce fogging
- May be re-usable (provided appropriate arrangements for decontamination are in place) or disposable
- Quality compliant with the below standards, or equivalent:
 - a. EU standard directive 86/686/EEC, EN 166/2002
 - b. ANSI/SEA Z87.1-2010

1.4. N-95 Masks

- Shape that will not collapse easily
- High filtration efficiency
- Good breathability, with expiratory valve
- Quality compliant with standards for medical N95 respirator:
 - a. NIOSH N95, EN 149 FFP2, or equivalent
- Fluid resistance: minimum 80 mmHg pressure based on ASTM F1862, ISO 22609, or equivalent
- Quality compliant with standards for particulate respirator that can be worn with full- face shield

1.5. Shoe Covers

- Made up of the same fabric as of coverall
- Should cover the entire shoe and reach above ankles

1.6. Face Shield

- Made of clear plastic and provides good visibility to both the wearer and the patient
- Adjustable band to attach firmly around the head and fit snugly against the forehead
- Fog resistant (preferable)
- Completely covers the sides and length of the face
- May be re-usable (made of material which can be cleaned and disinfected) or disposable
- Quality compliant with the below standards, or equivalent:
 - a. EU standard directive 86/686/EEC, EN 166/2002
 - b. ANSI/SEA Z87.1-2010

3. Triple Layer Medical Mask

- Three layered medical mask of non-woven material with nose piece, having filter efficiency of 99% for 3 micron particle size.
 - a. ISI specifications or equivalent

4. Gloves

- Nitrile
-
- Non-sterile
 - Powder free
 - Outer gloves preferably reach mid-forearm (minimum 280mm total length)
 - Different sizes (6.5 & 7)
 - Quality compliant with the below standards, or equivalent:
 - 1. EU standard directive 93/42/EEC Class I, EN 455
 - 2. EU standard directive 89/686/EEC Category III, EN 374
 - 3. ANSI/SEA 105-2011
 - 4. ASTM D6319-10

5. Body Bags - Specifications

- 1) Impermeable
- 2) Leak proof
- 3) Air sealed
- 4) Double sealed
- 5) Disposable
- 6) Opaque
- 7) White
- 8) U shape with Zip
- 9) 4/6 grips
- 10) Size: 2.2 x 1.2 Mts
- 11) Standards:
 - a) ISO 16602:2007
 - b) ISO 16603:2004
 - c) ISO 16604:2004
 - d) ISO/DIS 22611:2003

All items to be supplied need to be accompanied with certificate of analysis from national/ international organizations/labs indicating conformity to standards

All items: Expiry 5 years

* Due to scarcity of coveralls, and risk versus benefit, that as an emergency temporary measure in larger public interest, in present given circumstances, the fabric that cleared/passed 'Synthetic Blood Penetration Resistance Test' (ISO 16603) and the garment that passed 'Resistance to penetration by biologically contaminated solid particles (ISO 22612:2005) may be considered as the benchmark specification to manufacture Coveralls.' The Coveralls should be taped at the seams to prevent fluid/droplets/aerosol entry.

The test for these two standards (ISO 16603 and ISO 22612:2005), which can be performed in Indian laboratories are as per WHO Disease Commodity Package (Version 4.0)