



AHPI&ANBAI DOCUMENT FOR VERIFYING AUTHENTICITY OF PPE CERTIFICATES





Dear All:

The COVID-19 pandemic, has necessitated the use of PPEs in the Hospital setting, as a routine. The purpose is to safeguard the healthcare worker from getting infected with the virus. Unfortunately, the pandemic has happened so fast, and in such huge numbers that getting PPEs itself if of difficulty and of questionable quality. If the PPE is not of the stipulated standard, it does not serve its purpose, and the HCWs are left with doubts about being really protected. To help us identify a genuine certified product, Mr. Anil Jauhri, the former CEO of the National Accreditation Board for Certification Bodies (NABCB) India, has drawn up a well researched article. The other contributors to this document are Dr. Venkatesh Krishnamoorthy, Secretary, ANBAI and Dr. V.C. Shanmuganandan, Advisor, AHPI.

We have also attached the Ministry of Health Guidelines on specifications for PPE. While these guidelines mention the various ISO standards, towards the end of the document it is very clearly mentioned that these standards must be accompanied by certificate of analysis from National and International Organizations. These will have to be looked up in relevant website. For PPEs especially the coveralls and masks, the Ministry of Textiles has laid down the certification bodies for the different manufacturers across the country. Mr. Anil Jauhri has done a lot of groundwork to write up his document.

If any Institution wishes to seek his clarification, you may contact him at jauhrianil@gmail.com. He is willing to do his bit of social service for the healthcare professionals in these difficult times.

We hope this document serve to help the purchasing authorities in the hospitals to pay attention to the product they are buying.

Warm regards,

Annexure A

www.mohfw.gov.in Guidelines on Rational Use of PPE

MOH Specifications – April 2020

Personal Protection Equipment (PPE) -Specifications

(for Contact& Airborneprecautions)

<u>1.</u> PPE Kit

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

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/fingerloopsto anchorsleeves in place
- Quality compliant with following standard
 - a. Meets or exceeds ISO 16603 class 3 exposure pressure, or equivalent

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

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

Shoe Covers

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

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 snuggly 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
- Powderfree
- 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. BodyBags-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) IS016604:2004
 - 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)

VERIFYING AUTHENTICITY OF CERTIFICATES FOR PPEs

Anil Jauhri, Ex CEO, NABCB

As battle with Covid19 has significantly increased demand for Personal Protective Equipment (PPEs), a number of producers have come up in the market to produce PPE kits.

The guidelines on rational use of PPEs issued by MoH have specified specifications for PPEs which are generally ISO/ASTM/EU standards/regulations and accepts certificates from national/international organizations/labs – the latter is subject to interpretation.

As a result in the market, all kinds of certificates have been produced by suppliers to purchasers including govt procurement many of which are unauthentic.

Some examples of these certificates are attached – there are certificates for CE mark as well as ISO standards – CE certificates can only be issued by notified bodies of EC whereas authentic ISO certificates would be those which come from duly accredited certification bodies (CBs) and carrying logo of the accreditation body (AB) under the prevailing international system

The world market is full of private certification bodies issuing certificates to industry and it is important to distinguish an authentic certificate from many unauthentic, fake or fraudulent certificates going around. There are also private accreditation bodies outside the recognized international system and many of these CBs claim accreditation from such unauthentic ABs whose credentials are dubious.

The following guidance is provided to verify authenticity of certificates produced:

An authentic certificate should contain the following:

1. Name and address of the organization certified

2. Scope of certification describing its activities under certification – e.g. production, packing and sale of personal protective equipment like coveralls, shoe covers(broad list of products)

3. Standard (or sometimes scheme or regulation) against which certification is granted e.g. ISO 9001 or ISO 13485 (standard) or AS 9100 or FSSC 22000 (scheme) – in general guidance standards are not amenable to certification – these have to be formal, requirement standards or specifications for products or process

- 4. Date of issue and expiry of certificate
- 5. Unique identification number of the certificate
- 6. Name and address of the certification body (CB)
- 7. Logo of the certification body

8. Accreditation symbol indicating the name of the accreditation body (AB) which has accredited the certification body (in most countries, in the absence of any law requiring certification bodies to register, accreditation is the only way of recognizing a competent, authentic certification body)

9. IAF Mark (optional) – indicating that the certificate is covered under the Multilateral Mutual Recognition Arrangement (MLA) of the International Accreditation Forum (IAF) and hence is internationally equivalent and acceptable in the market

In order to judge the authenticity, the names of member ABs of IAF can be seen on its website **www.iaf.nu** – it also gives information on which accreditation bodies are signatories to IAF MLAs for specific schemes – QMS or EMS or FSMS. Once you locate the AB in a country, you can go to its website from the link given on IAF website and then on AB's website to verify if the CB is accredited. Then from the CB, you can verify the certificate because under international norms, CBs are obliged to help verify certificates issued by them. In case the certificate is issued under a scheme like IATF 16949 for auto sector or AS 9100 for aerospace sector or FSSC 22000 for food sector, it is possible to verify the certificates through the scheme owners also.

It may be noted that ISO is only a standards setting body and does not undertake any certification – hence use of ISO logo in any form on a certificate is misuse of its logo and you can assume that the certificate is not authentic.

It may also be noted that CE mark is Europe's regulatory mark and in case of PPEs, EC has a separate regulation under which Notified Bodies are designated only in Europe. The list is available at link https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir id=155501

There may be some branches or associates of NBs in India but any certificate must be from the NB listed in EC database.

In India, NABCB under QCI is the national accreditation bodies for certification bodies and any certificate bearing NABCB logo should be acceptable because NABCB will make sure the certificate is issued against a recognized standard following an acceptable process by a competent body.

An example of authentic certificate with NABCB logo is given below:



Examples of unauthentic certificates



XX - October XX - October XX - October

ity Control Certificatio on: D 4 Fran, Amer Vielan Yand, Doty 110 000, mile on 1829 Chansellin Hose no Park, Trans TR4 BUN, Convest, UK

un an FLORENCE

antil the sumafacturing conditions or the quality

Damel

08th May 2014 08th May 2014 07th May 2015 07th May 2017

Form QAT_10-M04, version 00, effective since March 25th, 2020

Certificate of Compliance



Certificate's Holder:

Zhejiang Ugly Duck Industry Co., Ltd. No. 2 Dongfang South Road, Ouhai District, Wenzhou City, Zhejiang Province, China.

Certification ECM Mark:



Product: Model(s): Medical protective clothing 2020313

Verification to:

EN 14126:2003

R 2016/425 (Personal Protective Equipment)

in issued on a voluntary basis and upon request of the manufacturer. It is opinion that the technical documentation received from the manufacturer is satisfactory for the the contermity mark above can be affixed on the products the seasons of the BURE Carry COND fils use.

Standard:

ation and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 31 March 2020

Expiry date: 30 March 2025

Reviewer Technical expert Amanda Payne



Approver ECM Service Director Luc a Bedonni



Ente Certificazione Macchine Srl Via Ca' Bella, 243 - Loc. Castello di Serravalle - 40053 Valsamoggia (BO) - ITALY 🖀 +39 051 6705141 👼 +39 051 6705156 🖂 info@entecerma.it 🐔 www.entecerma.it







The use of the CE mark on this document is

ILLEGAL AND CONFUSING!

Ente Certificazione Macchine Srl Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (80) - ITALY 2 +39 051 6705141 4 +39 051 6705156 🖂 info@entecerma.lt 🐔 www.entecerma.it



Certificate of Sompliance

This is to certify that

4WAY CLINIC AND CONSULTANCY

REGISTERED ADDRESS: 203 B, CARRARA BUILDING, HIRANANDANI ESTATE, THANE WEST - 400607, MAHARASHTRA (INDIA)

> Has been assessed by QCS and found to be Comply with the requirements of:

ISO 16603:2004

"Clothing For Protection Against Contact With Blood And Body Fluids - Determination Of The Resistance Of Protective Clothing Materials To Penetration By Blood And Body Fluids - Test Method Using Synthetic Blood"

For the following scope:

"PERSONAL PROTECTIVE EQUIPMENT (PPE KIT), COVID – 19 TEST KIT, 3 PLY FACE MASK & N 95 FACE MASK"

Certificate Number: QCS-2020-WCAY-07173

To verify this certificate please visit at <u>www.gacb.us</u>

Date of Certification: 07th Apr 2020 Date of Recertification: 06th Apr 2023 (Subject to the company maintaining its system To the required standard)



Authorized Signatory



1ST Surveillance Due: 06th Apr 2021

2ND Surveillance Due: 06th Apr 2022

Validity of this Certificate is subject to Annual Surveillance audits done successfully This certificate remains the property of QCS and must be returned whenever demanded QCS is an independent system product and personal assessment body QCS is accredited by Global Accreditation Certification Board (GACB) US OFFICE: Maryland Avenue, SW Washington, D.C. -20202 info@qcscertgroup.com, www.qcscertgroup.com