World Health Organization
REGIONAL OFFICE FOR Africa

COVID-19 RESPONSE

WORLD HEALTH ORGANIZATION REGIONAL OFFICE FOR AFRICA SUPPORTS THE COVID-19 RESPONSE

Certification and Quality Check of Personal Protective Equipment (PPE)

Guidance to Countries

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Certification and Quality Check of Personal Protective Equipment (PPE)

In response to COVID-19 pandemic countries have been supplied with personal protective equipment (PPEs) for health workers as a barrier from getting infected by COVID-19.

The high demand of PPE by countries has led to the local production and importation of sub-standards PPEs from different sources. During the use of these protective equipment, several countries have raised issues of their quality, the issue of recycling of PPE in some instances due to shortage. Insufficient knowledge deriving from inappropriate use of PPEs is another exacerbating factor leading to the infection of health workers.

The use of PPE is based on prior risk assessment for the safety of the patient, of healthcare worker (including cleaners, ambulance drivers, etc.) and the community. The safety of the beneficiaries of these PPE depends on the quality of product and the accessibility to them in the facility and on the market. The PPE should be of the best affordable price.

The IPC team should advise on appropriate procurement and use of PPE based on WHO recommended standards and international standard guidelines on PPE certification and quality check. These standards for certification and quality check may vary from a country to another.

In general, products are certified by recognized and well-known institutions according to a set of quality standards. Therefore, companies will seek for certification before putting their manufactured products on the market. Once this is obtained, quality should be maintained to keep trust in the quality of the commercialized product. In the procurement chain, buyers or users should request for an updated product certificate.

Many organisations and countries have management system, manufacturing process, service, and documentation procedure for standardization and quality assurance.

The approach to certification should be rigorous as it upholds the integrity of accredited certification. As certification process is complex and laborious some organisations including accredited certification bodies and experts worldwide help medical device manufacturers achieve certification. They also offer a wide range of services to help organizations achieve and maintain compliance as well.

The Emergency Global Supplies Catalogue (COVID-19) of 22.04.2020 gives an initial prioritized selection of items and is subject to constant review. This catalogue doesn't offer or guarantee allocation of supplies and the costs on it are only estimates.
As per principle of neutrality, WHO doesn't give guarantee on certification of PPE to avoid promoting a product from a manufacturer in detriment of the one of another manufacturer. Therefore, WHO can only advise institutions or governments on the matter and not take decision on their behalf. During emergencies, donors and governments are advised to seek for useful information related to PPE certification and quality check.

The following documents are also needed for certification verification and others are useful for quality check:

1. Name of the product and its intended use
2. Supplier's product code (catalogue number) & short description
3. Manufacturer's product code (catalogue number) & short description
4. Supplier's contact details, including link to web site with product catalogue
5. Manufacturer's contact details that may include the link to web site with product catalogue
6. Contact details of the person appointed for post-market surveillance including vigilance, customer complaints and recalls
7. Complete technical product specification
8. List of all supporting items/devices required, but not supplied

9. For sterile product: Sterilisation method and process (standard) followed for validation and routine control of sterilisation for medical devices; date of sterilisation; batch number (lot number); batch quantity
10. Recommended temperature and humidity for shipping, storage and use/operating
11. Instructions for use (IFU), brochure and training material
12. Estimated weight and volume
13. Photos of primary and secondary packaging with readable label information
14. Packaging and manuals in appropriate language and translation as required by the buyer.