Briefing Note

Quality Assurance Requirements for the Procurement of Masks and Respirators

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Background

There are different categories of personal protective equipment (PPE) that patients and health professionals can use to protect themselves against COVID-19. Some products that are meant to protect patients and limit the transmission of an infective agent between the hospital staff and the patient fall under medical device regulatory framework. Other masks intended to protect the user against health and safety risks will fall under the protective equipment regulation.

Regulations applicable to the PPE differ depending on its purpose as allocated by the supplier. Moreover, the name of the product varies from one regulation to another around the globe even if the intended purpose is quite similar.

Depending on the intended use allocated by the supplier, certain masks can satisfy both purposes and fall under the definition of both a medical device and a PPE. In this case, the product will have to satisfy all regulations applicable to both product categories.

Within a product category, suppliers often decline a product family in various types of products with different characteristics / performances which will have to satisfy different standards and tests procedures. Therefore, one of the critical points in dealing with such products is the adequate identification of the model / type within this family. Some suppliers maintain certain ambiguity to avoid facing stringent standards.

To ensure their sterility, products are subject to increased scrutiny by the relevant regulatory authority in which the product will be used via quality management systems requirements or other products specific procedures.

Based on all the above, the assessment of compliance with quality assurance (QA) requirements can become complex depending on intended purpose, regulatory framework and regulatory pathways. This briefing note aims to provide guidance in assessing compliance.

To mitigate supply shortage during the COVID-19 pandemic, some regulators (*e.g.*, the European Commission) have issued recommendations to allow, temporarily and under certain conditions, exceptions to their rules. The most relevant decisions are captured in this briefing note.

Scope

This briefing note provides detailed guidance to ensure compliance with the specific QA requirements for masks and respirators as defined in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (PSM guide). As per section 1.4 of the PSM guide, the Global Fund reserves the right to exercise the remedies set out under the grant agreement in the event of non-compliance.

This briefing note does not provide guidance on the quality and performance of fabric masks which are not covered by any quality assurance requirements.

Responsibilities

This briefing note is dedicated to recipients of the Global Fund funds. The main users of this briefing note are staff in charge of quality assurance within procurement departments/institutions to ensure the quality, safety and efficacy of the devices being purchased.

Limitations

This briefing note provides guidance on the QA requirements for masks and respirators, other core Personal Protective Equipment will be covered in the next version.

Because the Global Fund QA requirements are established on the basis of reliance mechanism to a stringent regulatory mechanism, this document should not be seen as a tool to assess the quality and performance of a medical device/core PPE which needs in-depth knowledge and experience of standards relevant to these products and related regulatory processes. A relevant notified body/regulator assesses the dossier, the recipient(s) ascertain(s) that the assessments have been done.

Reference to Global Fund Policy

(a) At procurement level:

As per Section 8.2 of the PSM guide, Principal Recipients are authorized to procure core personal protective equipment with grant funds when those products are:

- Pre-qualified under the WHO Prequalification Program.
- Compliant with the regulatory requirements and standards of one of the Founding Members of Global Harmonization Task Force (GHTF), namely, EU, USA, Canada, Australia, and Japan.
- Acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

(b) At pre-shipment stage:

As per Section 8.4 of the PSM Guide, to ensure that core personal protective equipment complies with Global Fund quality assurance requirements, Principal Recipients shall perform randomized pre-shipment sampling and testing through the following principles :

- Sampling and randomization performed according to WHO guidelines or other internationally recognized standard for sampling.[1]

[1] Available at https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:en

- Sampling to be done by an independent sampling agent.
- Testing to be done by an independent ISO 17025 accredited laboratory or certified by Good Laboratory Practices (GLP) with test methods available in its scope of accreditation.[2]
- Testing according to the internationally recognized standards or the approved specifications and methods.

(c) At post-marketing stage:

As per the section 8.5 of the PSM guide, Principal Recipients are required to monitor the quality of core personal protective equipment throughout the supply chain in line with relevant national, WHO or GHTF guidelines on Post-Market Surveillance of personal protective equipment and medical devices.

Description of the activities / Procedure

Overall strategy to ensure core personal protective equipment quality

The QA mechanism to ensure quality, safety and performance of masks and respirators procured with Global Fund funds is built on a multiple set of activities and actors along the product life cycle.

Principal Recipients are required to implement QA activities, as stated in PSM guide, through the following principles:

- The level of activities performed at post-market stage should be commensurate to the level of knowledge and assurance gained at pre-market stage. As such, there is no additional value to test products at pre-shipment stage if there is full assurance that the suppliers' production activities are supervised following stringent mechanism.
- No single authority has the workforce and expertise to perform all regulatory tasks for all products and reliance to other regulatory mechanism is strongly encouraged to avoid duplication and waste of resources.
- The level of effort should be commensurate to the level of risks.
- It is recommended to ensure quality at the design stage of the product lifecycle rather than to demonstrate quality by testing the finished product .
- Testing at post-shipment stage is only recommended in case of incident or other issue during the transportation of the products.
- To always embed the national regulators which has the primary responsibility to allow and maintain the access to their national market.

Procuring eligible products

The Global Fund QA requirements are based on the reliance mechanism to an existing regulatory authority or an existing group of regulatory authorities to ensure indirectly the quality, safety and performance of the masks and respirators. Implementing the reliance

[2] Available at https://european-accreditation.org/wp-content/uploads/2020/03/Accredited-laboratories-for-facemask-testing.pdf

mechanism means one does not need to re-do the whole assessment of product dossier of masks and respirators but to consider existing approval mechanism put in place by stringent regulatory mechanism such as:

- Pre-qualified under the WHO Prequalification Program.
- Compliant with the regulatory requirements and standards of one of the Founding Members of Global Harmonization Task Force (GHTF) (namely, EU, USA, Canada, Australia, and Japan).
- Acceptable for procurement using grant funds, as determined by the Global Fund based on the advice of the Expert Review Panel (ERP).

At the time of the issue of this briefing note, the WHO prequalification process for medical device or PPE was not operational and therefore no product can be procured based on this approval mechanism until further notice.

The same applies for the ERP mechanism. However, the involvement of the ERP can be decided by the Global Fund at any time to expand as necessary the supplier base of core PPE depending on the global context.

To facilitate the selection of an eligible product, the QA specialist can benefit from the Global Fund list of eligible products published and regularly updated on the Global Fund website.

Prequalification of suppliers

In the absence of list of eligible products, but to assess and confirm their eligibility, the recipient is requested to perform the following tasks to prequalify a supplier of a specific product:

(a) Request documentation

The QA specialist requests communication of all relevant documentation and other related evidence to ensure compliance with the Global Fund QA requirements for the new core PPE identified by procurement unit or specialists such as:

- Basic information on the products itself: brand name, product type, product family/category.
- Basic information on the suppliers responsible for putting the product on the market, the distributors (if different) and the authorized representative (for EU).
- Packaging and labelling information.
- Proof of approval, registration or listing by ex-GHTF members (see **annex 1** for EU documentation requested).
- Proof of any quality management system implemented (as necessary).
- Copy of any testing report, testing certificates.

This step should confirm the products type/category (MD or PPE) and relevant regulatory pathways (US, EU or others). Please refer to **annex 4** for EU risk classification and regulatory pathways and **annex 5** for USA regulation applicable to core PPE.

(b) Screen documentation

The QA specialist registers the documentation received and screens it for completeness and communicates to the procurement specialist whether any documentation is missing or not.

(c) Assessment of the documentation

The QA specialist identifies and confirms within the documentation provided by the suppliers the intended use/purpose, product type and/or category and that the product received is in line with the procurement request.

The QA specialist assesses the documentation for compliance, keeping in mind the regulatory framework and in line with the risk category allocated to the products. They will refer to relevant annexes for details of the required documentation to review depending on the type of product assessed and the available regulatory approvals.

- Check the labelling and the instruction for use to identify the main product information. Refer to ISO 15223 on symbols to be supplied by manufacturer for detailed information and **annex 2** for preliminary guidance.
- Check the regulatory documentation for CE marked products. Refer to **annex 1** for additional guidance on regulatory documentation for CE marked products. Review product documentation as follows:
    - Verify the declaration of conformity. Refer to **annex 6** for additional guidance (if applicable).
    - Verify the EC Type Certificate. Refer to **annex 7** for additional guidance (if applicable).
    - Verify the content of Production or Quality Management System certificate.
    - Refer to **annex 9** for additional guidance (if applicable).
    - For US FDA approved products, provide approval of 510(k) Approval and/or documentation of NIOSH certification. Refer to **annex 10** for additional guidance (if applicable).
    - For TGA, Health Canada and Japanese regulatory authority approved products, provide proof of marketing authorization.

(d) Verification of the testing report; as necessary

The QA specialist need to review the testing report submitted in line with the standards claimed and in particular:

- Content and conclusion of the report, in particular if all the tests are performed as per the claimed standards.
- The validity and scope of the laboratory accreditation.

- The quality of the accreditation body which accredited the testing laboratory. Refer to **annex 8** for additional guidance (if applicable).

(e) Analysis of sample

In some exceptional cases, the QA specialist may request a small sample of medical device equipment to review labelling and packaging.

The quality attributes of masks and respirators cannot always be tested at the procurement stage. The QA specialist can implement risk-based principles and focus on certain quality attributes such as sterility or Ethylene Oxide desorption which can be analyzed by an accredited laboratory. The basic principles for testing health products can be applied:

- Sampling to be done by an independent sampling agent or by staff/inspector of National Regulatory Authority (NRA) who have the mandate to take samples from health facilities as per national public health regulations.
- Testing to be done by an independent ISO 17025 accredited laboratory or certified by Good Laboratory Practices with test methods in its scope of accreditation.
- Testing to be done according to the internationally recognized standards or approved specifications and methods.

In case of testing, the QA specialist will check the results issued following the analysis against the specifications to conclude on compliance.

(f) National Regulatory Authority approval

As per section 8.11 of the PSM Guide, the Principal Recipient shall ensure that the procurement of core PPE complies with national regulation and related guidelines. The QA specialist should ensure that the procured masks and respirators are compliant with national regulation by asking for evidence of the authorization for marketing of the products issued by the authority in charge.

(g) Product prequalification

Based on the collected evidence, QA specialist prequalifies the product, documents the decision, informs relevant departments and includes products in the list of prequalified products. The Principal Recipients are encouraged to share the list of prequalified products with the Global Fund Secretariat on a regular basis.

(h) Product requalification cycle

QA specialist will perform a re-evaluation of the approved item in a frequency described in the internal procedure but no less than every 2 years to keep the approval status.

If information suggests that the product has been modified, a request for update of the documentation should be initiated.

If information on non-compliance or serious out-of-specifications are provided to the QA specialist, the approval status should be reviewed and confirmed.

(i) Product re-approval (or disapproval)-review of the prequalification status

Three months before the end of the approval status, the QA specialist requests for an update of the documentation provided, reviews the acceptability of the product and decides on its re-approval and updates the relevant records/list of eligible products.

(j) Falsified certificates

The high demand of PPE by countries has led to the local production and importation of substandard PPEs from different sources. Falsified or fraudulent certificates have been identified around the world as a mechanism to mislead procurers pretending to prove the conformity to EU rules. Among falsification instances, we can highlight the following practices:

- Certificate issued by an authority which has no delegation for the product or the regulatory pathway. (e.g., a Notified Body for PPE issuing a certificate for a medical device).[3]
- Certificate issued by an entity which is not a Notified Body for the said products.
- Certificate issued by a laboratory that is not accredited.
- Certificate issued on voluntary basis instead of a regulatory basis.
- Certificate issued by a testing entity not entitled to issue EC certificate while only EU Notified Bodies can issue EC certificate.
- Certificate not stating adequate scope in line with EC regulations i.e., certifying the technical documentation.

The QA specialist is advised to cross-check in case of any suspicious, new or unknown suppliers with information made available by stringent regulatory framework such as:

- EU safety information available at https://www.eu-esf.org/covid-19/4513-covid-19https://www.eu-esf.org/covid-19/4513-covid-19-suspicious-certificates-for-ppesuspicious-certificates-for-ppe.
- Swissmedic information with example of misleading certificates available at https://www.swissmedic.ch/swissmedic/en/medicrime/news/warnings/coroavirus-nichtkonforme-med-gesichtsmasken.html.
- Safety Gate: the EU rapid alert system for dangerous non-food products by selecting protective equipment available at https://ec.europa.eu/safety-gatealerts/screen/search?resetSearch=true.

Procurement of prequalified products

Procurement should be based on the list prequalified by the Principal Recipient or Procurement Agent as per the above procedure.

[3] Verification of notified bodies, their mandate and validity available at https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=country.notifiedbody&cou_id=756

Pre/post shipment inspection and testing

The Global Fund does not recommend routine pre-shipment inspection and testing for all procurements of masks and respirators; this should be done randomly instead. This is based on the acknowledgement that:

- The quality of the products should be given at pre-qualification stage.
- Testing samples cannot demonstrate assurance of quality except if performed as per international standards allowing adequate representativity which is not implementable because of cost implications.
- Such mechanism can be influenced directly or indirectly by suppliers even if an independent inspection and sampling agent is recruited.

The randomization should be established on a risk-based approach, where the pre-shipment testing can be triggered by the level of assurance provided by the documentation collected at prequalification stage, the procurement history, the information collected from the field on the marketed products, as well as taking into consideration the procurement volume. Refer to **Annex 12** on suggested approach for randomization.

However, the Global Fund Secretariat encourages to perform post-shipment inspection at the time of the reception of the goods as per good distribution practices and in line with procedures established by the receiving entity (actors involved in procurement and supply management activities). This step should be confirmed by visual inspection and review or import documentation that the products received are in line with the purchase order and the specifications.

Among the visual inspection, the verification of the labelling and packaging requirements should and other verifications should be performed on quantity and cleanliness of the secondary package.

The Global Fund does not advise conducting routine post-shipment testing, except if the information collected on transit and logistic conditions during the post-shipment inspection indicate the likelihood of a risk on the quality or the performance of the products procured.

In-country quality monitoring and reporting

Principal Recipients shall monitor and take measures to ensure adequate monitoring of the quality of masks and respirators throughout the supply chain in line with relevant WHO or Founding Members of Global Harmonization Task Force guidelines.

In-country quality monitoring consists of supplementary activities rather than relying on one specific activity such as quality testing. For example:

- Visual inspection of the packaging of the products, its labelling and packaging. Falsifications or identification of non-compliance can be captured by reviewing the content of packaging and labelling such as spelling error, inadequate mention of

standards, lacking date of edition. The best approach is to compare to the labelling and packaging documentation received at prequalification stage.

- Physical examination of the products, measurement of size, verification of the number of layers within a surgical mask, verification of the aspects of the membrane or through the light, verification of the burning behavior of a membrane or putting drops of water are also indicative procedures to identify suspicious products without having to perform complex and lengthy testing procedures. The best approach is to compare also with the samples requested at the time of prequalification.
- Refer to **annex 3** for full testing performance standards for the assessment of PPE/MD. Time consuming, costly and lengthy procedure to demonstrate or confirm the compliance of a product that needs to be employed when there is a presumption of non-compliance to confirm any doubt on product quality or failure.

Principal Recipients are required to work in close collaboration with the relevant National Regulatory Authority to avoid overlaps and to enhance the current existing mechanisms. In designing such activities, it is advisable to consider a risk-based approach based on the information collected at all steps of the process such as:

- History of compliance/ non-compliance.
- Procurement channel (emerging suppliers versus established channels and partners).
- Feedback/complaints from users.
- Information collected from global networks.

As per current best practices, Principal Recipients are required to describe activities, timelines, actors and responsibilities in a detailed quality control plan for a specified period of time.

Quality control testing

(k) Sampling

The number of samples taken should be enough to perform two times the requested testing activities. The first set is used for the testing and the second set is used in case of discrepancies between the laboratory and the supplier's results.

Sampling should be based on ANSI/ASQC Z1.4 or ISO 2859-1, with the following advice for surgical masks.

ASTM F2100	EN 14683
AQL 4% for BFE, PFE and Delta P	Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbiological Cleanliness

ASTM F2100	EN 14683
32 masks for Synthetic Blood (Pass=> 29 passing; Fail=<28 passing)	32 masks for Synthetic Blood (Pass=> 29 passing; Fail=<28 passing)
14 masks for Flammability	

(l) Selection of quality control laboratory

The testing activities should be performed by a laboratory that is independent from the manufacturer or supplier. The laboratory should have a quality assurance system in place according to ISO 17025 accreditation standard or to the OECD principles of Good Laboratory Practices (GLP).

Ideally, all methods requested for testing the specifications should be within the scope of accreditation of the laboratory. If this is not possible, the testing report should clearly state which tests were performed out of the scope of accreditation/certification.

The list of the laboratories which are accredited and have been identified by the Global Fund QA Team as acceptable for testing of masks and respirators can be found here.

(m) Contractual agreement

A contract should be established between the testing laboratory and the party requesting the testing.

(n) Testing specifications

Under current practices, the sample analysis should consider the whole set of performance tests as per the standard claimed. In case a specific deficiency is clearly identified the testing activities can focus on the specific parameters in question. Refer to **annex 11** for a standards comparison of main critical parameters (EU versus US).

A list of eligible masks and respirators is regularly updated and published by the Global Fund Quality Assurance Team. Recipients can refer to the last version available on the Global Fund website.

(o) Testing method

Except if a specific directive is given to the testing laboratory by the Principal Recipient, the testing method should be performed according to the methods prescribed by the standard claimed.

Depending on the scope of activities of the testing laboratory, laboratory can be requested to review the labelling and packaging requirements to confirm compliance with the prescribed standards.

(p) Testing report

The laboratory should provide comprehensive testing report of the results, which must be signed by the person in charge. Guidance on the content of a testing report is provided in **annex 8**.

(q) Decision for release

The decision to release the products rests solely with the Principal Recipients. However, delegation can be organized under specific contractual arrangements with the respective procurement agents.

This decision will be based on the satisfactory demonstration of the compliance with the standards via the outcome of the testing report.

The final decision to release should be made by an authorized person, preferably a pharmacist or a chemist and /or under the direct supervision of a pharmacist or chemist.

In case of full compliance, the authorized person records the decision and allows the release of the batches as per the planned arrangements with the procurement agent.

Quality deficiencies, non-conforming and counterfeited masks and respirators

If Principal Recipients or procurement agents discover an irregularity during the procurement of a product under Global Fund grant funds (e.g., suspicion of counterfeit products or falsified certificates, poor quality practices), it should be reported within five working days to the Global Fund secretariat using the quality complaint form available on the Global Fund webpage[4], sent to the QA Team at: HealthProductQualityAssurance@theglobalfund.org. The QA Team receives suspect reports, checks them and based on the involved risks, takes necessary measures, including if necessary, consulting other relevant authorities.

As per the PSM guide section 8.10, Principal Recipients shall develop and maintain a system acceptable to the Global Fund for reporting to the appropriate regulatory authorities any defects relating to core personal protective equipment and for facilitating communications with manufacturers, procurement agents, distributors and end-users in the event of defects of core personal protective equipment. Investigations must be performed in line with the contractual arrangement between procurement agent and recipients, and any impacted products should be maintained under quarantine conditions until the end of the investigations performed by the supplier in collaboration with the procurement agent. Regular updates should be provided to the QA team for further guidance or advice.

Principal Recipients and procurement agents will coordinate investigative work with the contracted laboratory and/or at the supplier until root causes or probable root causes have been established. Further release decisions after investigation closure must be agreed upon

[4] A notification will be sent to PRs once the quality compliant form is published on the website

with the Global Fund QA team. Recipient/procurement agent(s) will summarize a proposed course of action and provide detailed information at the request of Global Fund QA team.

The Global Fund QA team will assist in timely decision-making on the affected materials and keep trend information on quality control experiences for particular suppliers/products for QA purposes. Where needed, trend information will be fed back to the WHO prequalification team or ERP panel.

Communication of the test results

As per section 8.9 of the PSM Guide, Principal Recipients are required to provide Global Fund with the results of all quality control testing via e-mails to the relevant Country Teams/Health Product Managers, copying the Global Fund QA Team at HealthProductQualityAssurance@theglobalfund.org not later than 2 weeks after receipt of the results.

Principal Recipients shall make the necessary arrangements between the procurement agent and the quality control laboratory so that a documented procedure is in place and implemented for ensuring the adequate communication of these results. As per section 8.9 of the PSM guide, Principal Recipients understand that the Global Fund is authorized to use these results.

Record retention

All records related to the activities described above should be archived by the Principal Recipient or the procurement agent acting on its behalf for at least seven years except if different retention rules applied (e.g., UN agencies). Records should be made available to the Global Fund upon request.

Costs related to quality control activities

As per section 8.8 of the PSM Guide, the cost of conducting quality control activities of core PPE may be included in the grant budget, as part of the procurement and supply management cost for the relevant program, subject to Global Fund approval.

Abbreviations

ERP	External Review Panel
EU	European Union
GHTF	Global Harmonization Task Force
GLP	Good Laboratory Practices
HPMs	Health Product Management Specialist
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
MD	Medical Device
NIOSH	National Institute for Occupational Safety and Health
NB	Notified Body
NRA	National Regulatory Authority
OECD	Organization for Economic Cooperation and Development
PPE	Personal Protective Equipment
PR	Principal Recipient
QA	Quality Assurance
US FDA	United States Food and Drug Administration
WHO	World Health Organization

Glossary of Terms

Authorized representative refers to a manufacturer established within or outside the European Union (EU), a legal entity appointed by the manufacturer in the EU to act on its behalf in carrying out tasks in the applicable EU harmonization legislation. Depending on the applicable legal framework, a manufacturer established outside the EU may not be obliged to have an authorized representative.

Core personal protective equipment means equipment and an interchangeable component to be worn or held by a person for protection against harmful biological agents to that person's health or safety. Depending on its intended purpose, such equipment can be classified as a medical device or as personal protective equipment or both. In this briefing note, core personal protective equipment includes such items as apron protection, gloves, face shields, masks, respirators, gowns and protective goggles.

Good Laboratory Practices (GLP). Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

Global Harmonization Task Force (GHTF) refers to the group established to encourage convergence in regulatory practices to ensure safety, effectiveness, performance and quality of medical devices, promoting technological innovation and facilitating international trade and is comprised of representatives from medical device regulatory authorities and other regulated industry participants. As of 2012, GHTF has been replaced by the International Medical Device Regulators Forum.

Inspection means the act, by a competent authority, of conducting an official review of documents, products, facilities, records, quality assurance arrangements or any other aspects deemed necessary by the authorized official.

International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the GHTF and aims to accelerate international medical device regulatory harmonization and convergence.[5]

Medical device refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the following specific medical purpose(s):

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.

[5] Further details are available at *www.imdrf.org*.

- Supporting or sustaining life.
- Control of conception.
- Disinfection of medical devices.
- Providing information by means of in vitro examination of specimens derived from the human body.

And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Surgical mask means a disposable medical device covering the mouth, nose and chin of the wearer that is designed to block bacteria and infectious agents transmitted by large-particle droplets from the wearer's mouth and nose when the wearer exhales. Some surgical masks can offer splash resistance against splashes of liquid, for example, patient's blood during surgery, but such masks are not designed to protect the wearer against inhaling airborne bacteria or virus particles. Such device may also be worn by patient and other persons to reduce the risk of infection spreading in epidemic or pandemic situation.

Notified body means an organization designated by an EU country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The European Commission publishes a list of such notified bodies.

Personal Protective Equipment (PPE) means an equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety.

Procurement (service) agent means a person specialized in procurement business and acts for another called the principal in dealing with third parties in matters relating to procurement such as Manage Requisitions, Manage Purchase Orders, Manage Purchase Agreements and related negotiations.

Quality control is part of quality monitoring and includes all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that health products conform to established specifications.

Quality monitoring means all activities undertaken to ensure that health products continue to conform to the manufacturer's established quality specifications during the storage, distribution and use of such products, including quality control in a laboratory.

Recipient means any entity that receives Global Fund funds (such as a grantee, Principal Recipient, sub-recipient, sub-sub-recipient or procurement agent).

Regulatory Authorities of the Founding Members of the Global Harmonization Task Force. The regulatory authorities of the United States, the European Union, Japan, Canada and Australia.

Respiratory mask (FFP2, N95) means a personal protective equipment as it is designed to protect the wearer against particulates such as dust particles and various viruses in the air,

including COVID-19. This type of mask, unlike the surgical mask, protects the wearer from inhaling infectious agents or pollutants in the form of aerosols, droplets or small solid particles. Respirators are used by healthcare workers, mainly to protect themselves during aerosol generating procedures.

Testing means the act of determining one or more characteristics of a product or an equipment according to a procedure or method. Results of testing activities are usually recorded in a testing report.

References

1. Guide to Global Fund Policies on Procurement and Supply Management of Health Products
   https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf

2. The PPE regulation Regulation (EU) 2016/425 of 9 March 2016 on personal protective equipment

3. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
   https://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

4. Conformity assessment procedures for protective equipment EU Guidance Conformity assessment procedures for equipment dated 27 March 2020

5. Guidance for Industry: Surgical Masks – Premarket Notification 510(k) Submissions
   https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks

6. Surgical masks and N95 respirators differences
   https://www.cdc.gov/niosh/npptl/pdfs/UnderstandDifferenceInfographic-508.pdf

7. FDA PPE: https://www.fda.gov/medical-devices/personal-protective-equipment-infection

8. NIOSH approved N95 Particulate Filtering Facepiece Respirators
   https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1-b.html

9. OECD Principles of Good Laboratory Practice (GLP) and GLP Compliance Monitoring
   https://www.oecd.org/chemicalsafety/testing/overview-of-good-laboratory-practice.htm

10. Commission Recommendation (EU) 2021/1433 of 1 September 2021 on conformity assessment and market surveillance procedures within the context of COVID-19
    https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021H1433

Annexes

Annex 1. CE documentation required for the offer of PPE/MD product

Denomination	Regulation and class	Notified Body	EC Declaration of Conformity	MDD- EC Production Certificate for sterile state	MDR-EC Quality Management	PPE-EC Type Examination Certificate	PPE-EC Certificate	On-module CII or D Test report as per standards claimed
Surgical face mask	MD /Class I		X					X
Surgical face mask - fluid resistant	MD / Class I		X					X
Surgical face mask - Sterile	MD / Class Is	X	X	(X)	X			X
Respiratory mask (FFP2, FFP3)	PPE Class 3	X	X			X	X	X
Respiratory mask (FFP2, FFP3) - fluid resistant	PPE Class 3	X	X			X	X	X
Respiratory mask for medical purpose (FFP2, FFP3)	MD Class I -PPE Class 3	X		X			X	X

Annex 2. Checking labelling and instructions for use

The label must bear the following particulars:

a) The trade name and address of the manufacturer. For devices imported into the country in view of their distribution in the country, the label, or the outer packaging, or instructions for use, shall contain the name of the authorized representative of the manufacturer established within the country or of the importer established within the country, as appropriate.
b) The details strictly necessary for the user to identify the device and the contents of the packaging.
c) Where appropriate, the word “STERILE”.
d) Where appropriate, the batch code, preceded by the word “LOT”, or the serial number.
e) Where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.
f) Where appropriate, an indication that the device is for single use.
g) Any special storage and/or handling conditions.
h) Any special operating instructions.
i) Any warnings and/or precautions to take.
j) Year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number.
k) Where applicable, method of sterilization.
l) Number of this European Standard.
m) Type of mask (I, II, IIR).

Note: In EU the CE marking logo is mandatory for both products and labelling.

Note: The EN ISO 374 VIRUS standard measures the ability of gloves to protect user against bacteria, fungi and viruses.

Annex 3. Main performance standards for the assessment of PPE/MD

In all jurisdiction, the application of product standards is a means to demonstrate performance of the products regulated. The challenge is then to identify the applicable standards which should be satisfied depending on the intended purpose as allocated by supplier.

Denomination	EU	US Standards	Australia/ New Zealand	Japan	Canada
Surgical mask	EN 14683: 2019	ASTM F2100-19	AS/NZA 4381:2015	JIS T 9001	ASTM F2100-19 or EN 14683: 2019
Respiratory mask	EN 149:2001	NIOSH 42 CFR 84	AS/NZA 1716:2012	JIS T 8150	CSA Z94.4.1

Annex 4. EU risk classification and pathways

For masks, the EU framework has established two regulatory frameworks:

- **Medical face masks or surgical face masks** are products falling within the scope of the EU legal framework on medical devices – Directive 93/42/EEC (MDD), to be replaced by Regulation (EU) 2017/745 (MDR) as from 26 May 2021.
- **Protective face masks or respirators** are considered as personal protective equipment (PPE) and hence fall under the scope of Regulation (EU) 2016/425 (PPER).

Each of the two legal frameworks fully harmonizes the performance requirements for the products that it covers to ensure protection of the health and safety of users and requires the affixing of the "Conformité Européenne" (CE) marking to the products.

Medical devices

Risk classification

i. Class I medical devices

Class I medical devices that are not provided as sterile have the lowest perceived risk. The manufacturers of such devices will make its own certification meaning without the involvement of a Notified Body and formally declare its compliance with the applicable requirements of the Medical Devices Regulation (MDD) via a written statement. As there is no certification as such, the compliance is demonstrated by the supplier under the format of an EU (self)-declaration of conformity (as per annex VII of the MDD or Annex II and III of the MDR).

ii. Class I medical devices delivered as sterile

If the surgical face mask is delivered in a sterile state, the supplier should in addition request the intervention of a Notified Body for the aspects of manufacturing concerned with securing and maintaining sterile conditions depending on the regulatory pathway he decided to take.

The Notified Body is not per se a regulatory authority but it receives delegation of authority for such regulatory activities by each EU member state which is also in charge of its monitoring.

For the surgical face mask delivered **in sterile state** the following EU regulatory pathways are recalled in the following table:

EU Regulation	Regulatory pathway	Name of document issued by Notified Body*
EU MDD 93/42/EEC	Annex II.3 (Section 4)	EC Certificate Quality Assurance System
	Annex IV EC Verification Full production of batch testing	No specific certificate issued
	Annex V EC Production Quality Assurance	EC Certificate – Production Quality Assurance Directive 93/42/EEC on Medical devices
	Annex VI Product Quality Assurance	No specific certificate issued
EU MDR 2017/745	Annex IX Quality Management Systems (Chap I)	EU Quality Management System certificate.
	Annex XI (Product Conformity Verification, Part A)	EU Quality Assurance certificate

*However, an organization designated as an NB may issue other certificates e.g., in its position as an accredited certification body. Those certificates must not be purported to have been issued by the NB.

Independently from the MD risk classification **but based on EU standard EN 14683**, Surgical masks are classified into Type I and Type II depending on their filtration efficiency. A type IIR offers additional protection against liquid splashes.

Personal protective equipment

Risk classification

For masks and other equipment which aim to protect the user, the PPE Directive (EU) 2016/425 categorizes products into three groups concerning the level and type of protection. Each category determines the extent of control on the manufacturer's production and quality system, as well as the level of involvement of a Notified Body.

i. Category I – Simple PPE

The PPE, classified as category I, protects users against minimal risks and does not provide protection against severe hazards such as ionizing radiation or harmful biological elements. Hence, conformity assessment procedure does not include Notified Body testing and evaluation. By consequence, the manufacturers can self-declare compliance with the respective legislation.

ii. Category II – Intermediate PPE

This category includes medium-risk PPE, such as safety spectacles and goggles, high visibility clothing, bump caps and industrial helmets. The conformity procedure requires a Notified Body assessment.

iii. Category III – Complex PPE

PPE of complex design intended to protect the user against any risks with severe consequences. Such risks may cause serious and irreversible harm to the user's health and the immediate effects of which the user, presumably, cannot identify in sufficient time. The procedures envisage in all product categories for the involvement of a Notified Body.

Regulatory pathways

The compliance process of complex PPE includes the intervention of a notified body in charge to perform various activities depending on the regulatory pathways chosen by the suppliers. The notified body receive delegation of authority for such regulatory activities by each EU member state which is also in charge of its monitoring.

The notified body performs assessment of the product design (EC-type examination) and conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) set out in annex VII or Conformity to Type based on quality assurance of the production process (Module D) set out in annex VIII.

The compliance with EU standards can only be confirmed by EU testing laboratories with an accreditation to do so. Under exceptional circumstances, some EU member states for a time limited period recognized laboratories or inspection bodies accredited by the Chinese authority. This derogation came to end on the 31 May 2022.[6]

EU Regulation	Regulatory pathway	Name of document issued by Notified Body
EU PPE 2016/425	Annex V - EU type-examination (module B) + Annex VII Internal Production control	EU type-examination Certificate Internal production control certificate – Module C2
	Annex V - EU type-examination (module B) + Annex VIII Quality Assurance of the production	EU type-examination Certificate EC Certificate – Production Quality Assurance-Module D

[6] Commission Recommendation (EU) 2021/1433 of 1 September 2021 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

Annex 5. USA regulations applicable to core PPE

Masks: In the United States, personal protective equipment is regulated by two different entities depending on the intended purpose of the products allocated by the suppliers.

Surgical masks: All surgical masks to be used in medical environment are regulated as medical devices. They must follow the U.S. Food and Drug Administration (FDA) regulations and meet specific performance standards for protection and clearance by the FDA under the section 510(k) of the Food, Drug and Cosmetic Act allowing the market of a medical device in the US.

Respirators: The National Institute for Occupational Safety and Health (NIOSH) is the U.S. Government agency responsible for the certification and approval of respiratory protective devices for occupational use. It also addresses quality assurance requirements for the manufacturing of respiratory protective equipment. The approach to approval is that anybody can manufacture and sell any type of respiratory protective device, but only those that meet or exceed all of the requirements established in the 42 CFR 84 standards are acknowledged by NIOSH, and only those that have been NIOSH-certified may be marketed as a NIOSH-approved respirator.

Surgical Respirator: Such products are both approved and cleared by the FDA and evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR part 84.

Annex 6. Assessing EC Declaration of Conformity

For surgical masks which are not assessed by medical body, the EC declaration is done by the supplier alone and is called self-declaration. Because a Notified Body intervenes for core PPE in the regulatory processes/pathway, the supplier cannot issue a self-declaration.

It is important to review the content of the EC Declaration of Conformity to confirm its validity and cross-check with the information collected via labelling and instructions for use and other collected evidence such as EC Type certificate, Testing Certificate.

If a product falls under the scope of two or more EU legislative acts providing for the CE marking, a single EU Declaration of Conformity must be drafted and signed by the manufacturer, declaring conformity with the applicable two or more pieces of legislation.

A valid EC or EU Declaration of Conformity must be signed by the manufacturer itself, and should include the following elements:

a) The identification and description of the product, the product type and/or product code. Please cross-check with other documentation collected and product labelling and/or photo.
b) The EU legislative act(s) and date of issue to which conformity is claimed.

For Medical Devices:

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (hereafter referred to as MDD)
- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereafter referred to as MDR, fully applicable as from 26 May 2021).

For PPE:

- Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (hereafter referred to as PPER).

c) The name and address of the manufacturer.
d) The name and address of the authorized representative, where applicable i.e., for manufacturers located outside the EU.
e) A statement that the declaration is issued under the sole responsibility of the manufacturer.
f) The conformity assessment procedure(s) applied. Please cross-check with the possible alternative procedure in the relevant annex of this briefing note.
g) References to the relevant harmonized European standard(s) or common specification(s) used, where applicable. Please cross-check with the list of standards provided in the relevant annex on this briefing note.

h) The name and the 4-digits identification number (NB xxxx) of the Notified Body and reference to the certificate(s) issued, where applicable; please cross-check with the list of Notified Bodies designated as such by their member states.

The Notified Body should be designated for the regulatory framework (medical device or PPE) and also the procedure in question (quality system or examen CE type) as not all the Notified Bodies may have the same scope of work by product category and by regulatory pathways. For MDD, the information is available at:

- https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13 For MDR:
- https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34 For PPE:
- https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=155501

Because of mutual recognition agreement between EU and other countries, for example, in Switzerland and Turkey some entities perform their assessments which are similar to EU Notified Bodies and are recognized with the same value. Please cross-check with the following webpage of the NANDO database for mutual recognition agreement of conformity assessment body: NANDO database.

Depending on the Notified Body, you may have opportunity to cross-check the validity of the certificate of the said products by checking on the Notified Body webpage.

i) Date of issue of the declaration.
j) Identification and signature of the manufacturer.

Annex 7. Assessing EC Type Examination Certificate

It is important to review the content of the EC Type Examination Certificate to confirm the validity of the certificate and to cross-check with the information mentioned in the EU Declaration of Conformity.

The EU type-examination certificate shall contain at least the following information:

a) The name and identification number of the Notified Body.

b) The name and address of the manufacturer and if the application is lodged by the authorized representative, the latter's name and address.

c) Identification of the PPE covered by the certificate (type number).

d) A statement that the PPE type complies with the applicable essential health and safety requirements.

e) Where harmonized standards have been fully or partially applied, the references of those standards or parts thereof.

f) Where other technical specifications have been applied, their references.

g) Where applicable, the performance level(s) or protection class of the PPE.

h) For PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model.

i) The date of issue, the date of expiry and, where appropriate, the date(s) of renewal.

j) Any conditions attached to the issue of the certificate.

For category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19 of regulation (EU) 2016/425 of the European parliament and of the council of 9 March 2016 on personal protective equipment[7].

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0425

Annex 8. Assessing EC testing report

It is important to review the content of the EC Testing report to confirm the validity of the EC Type Examination and to cross-check with the EC Declaration of Conformity.

The test report should contain at least the following information:

a) The laboratory test report number.
b) The name and address of the laboratory testing the sample.

   Please check if the laboratory is accredited to perform the tests as requested by the applicable standards. The list of accredited laboratories for the scope EN 14683 and/or EN 149 can be downloaded at the European Accreditation Organization (EAO) website.

   In order to confirm the EU derogations regarding testing laboratories accredited by the China National Accreditation Service (CNAS) available at (https://www.cnas.org.cn/english/photonews/04/902561.shtml), please cross-check if the certificate has been issued after the 1st October 2021.

c) The name and address of the accreditation body which has accredited the testing laboratory, as well as the accreditation number issued for the laboratory.

   Please cross-check with the list of accreditation body from EU available at https://europeanaccreditation.org/ea-members/directory-of-ea-members-and-mla-signatories/ or globally available at https://ilac.org/ilac-membership/members-by-economy/.

d) The name and address of the originator of the request for analysis, if different the name and address of the original manufacturer and, if applicable, those of the repacker and/or trader.

e) The name, description and batch number of the sample, where appropriate.

f) The date on which the sample was received.

g) An introduction giving the background to and the purpose of the investigation.

h) A reference to the specifications used for testing the sample or a detailed description of the procedures employed, including the limits; as well as any exclusions which could limit the impact of the evidence provided.

i) The laboratory registration number of the sample.

j) The results of all the tests performed or the numerical results with the standard deviation of all the tests performed (if applicable).

k) Discussion of the results obtained; whether the sample(s) complies (comply) with the requirements.

l) A conclusion as to whether the sample(s) was (were) found to be within the limits of the specifications used, or for a sample for investigative testing, the substance(s) or ingredient(s) identified.

m) The date on which the test(s) was (were) completed.

n) The signature of the head of the laboratory or authorized person.

o) The expiry date or retest date, if applicable.

Annex 9. Assessing production or other Quality Management System certificate

It is important to review the content of the Production or other Quality Management System certificate to cross-check with the EC declaration of conformity.

The certificate should contain at least the following information:

a) The name and location(s) of the entity implementing the Quality Management System.

b) The name and address and the 4-digits identification number (NB xxxx) of the Notified Body where applicable. Please cross-check with the list of notified bodies approved for the said product and legal framework.

c) The certificate number allocated to the entity audited (specific to the supplier's location and Notified Body).

   Please cross-check with the list of Notified Bodies in the EU approved for the said product and legal framework (same as EC Declaration of Conformity).

d) The reference to the Quality Management System standards used for auditing or a detailed description of the procedures employed (such as quality production).

e) The brief description of the scope of the Quality Management System audited both mentioning the life-cycle steps and products category supervised.

f) The conclusion as to whether the location was found compliant with standards(s) used for reference.

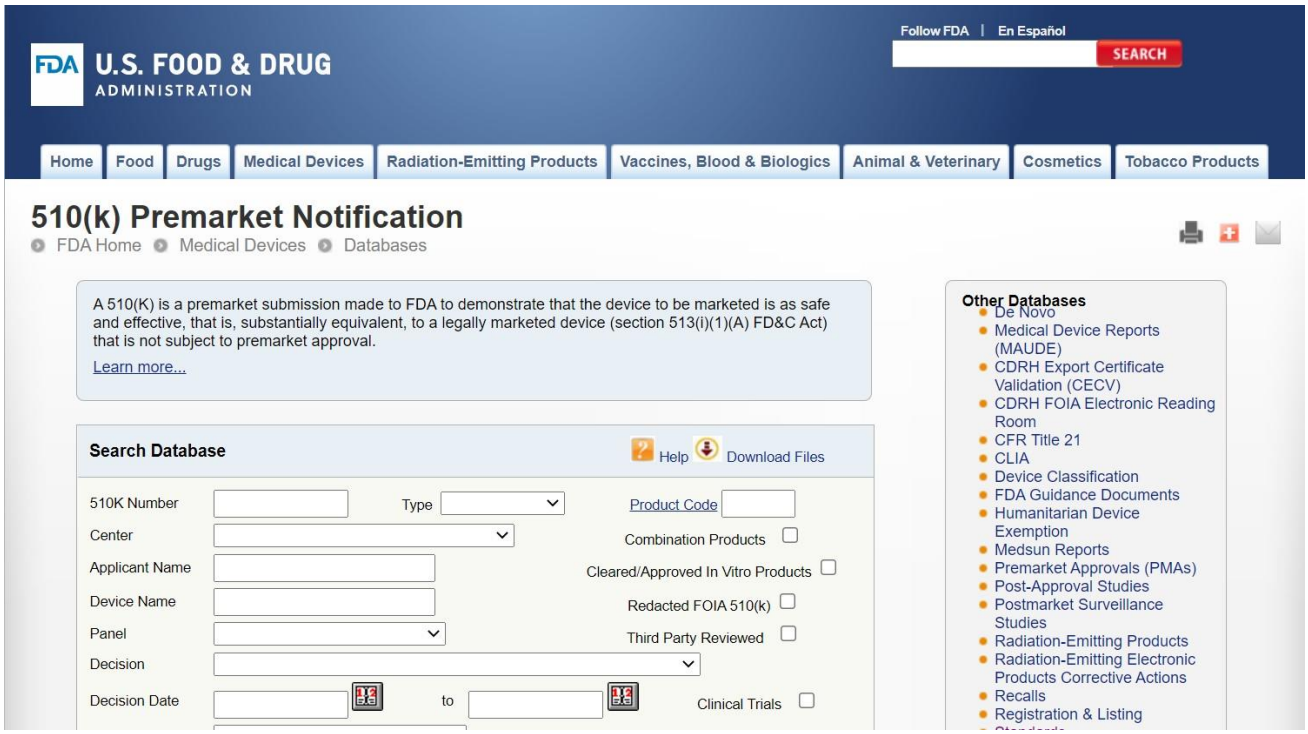
g) The signature of the head of the Notified Body.

h) The issue date and expiry date / validity, if applicable.

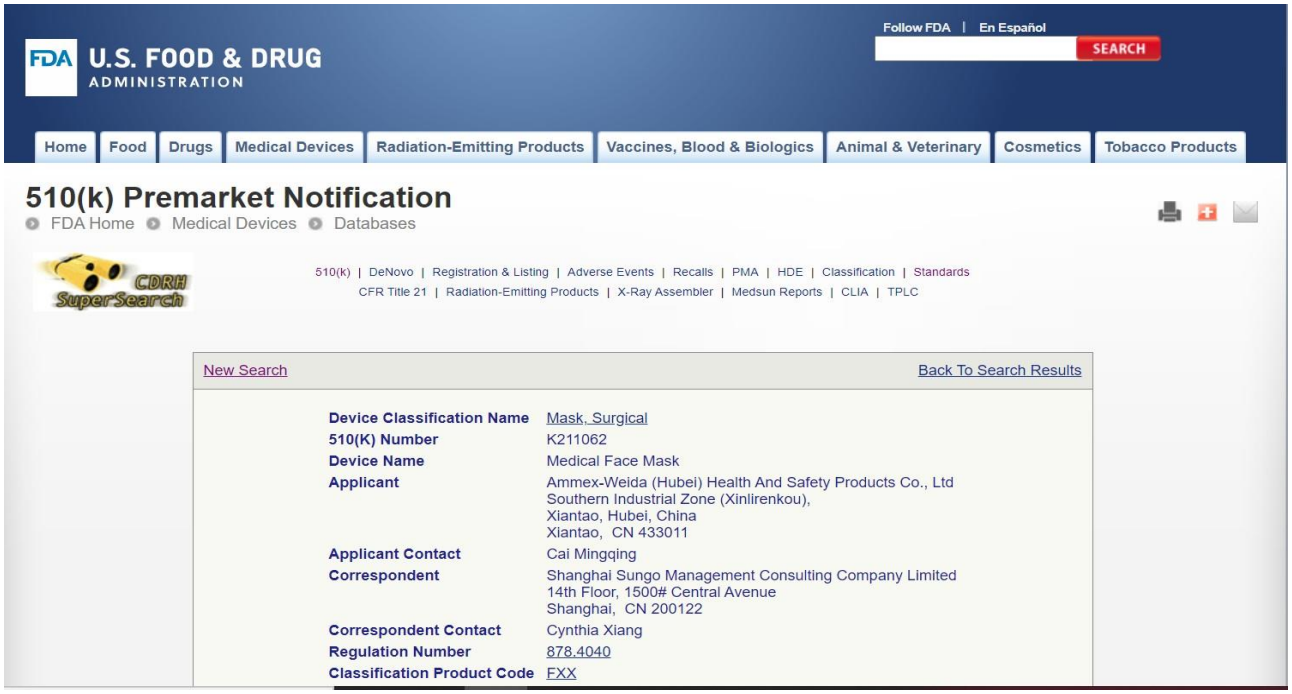
Annex 10. Assessing FDA approved products

Medical device approved by the FDA

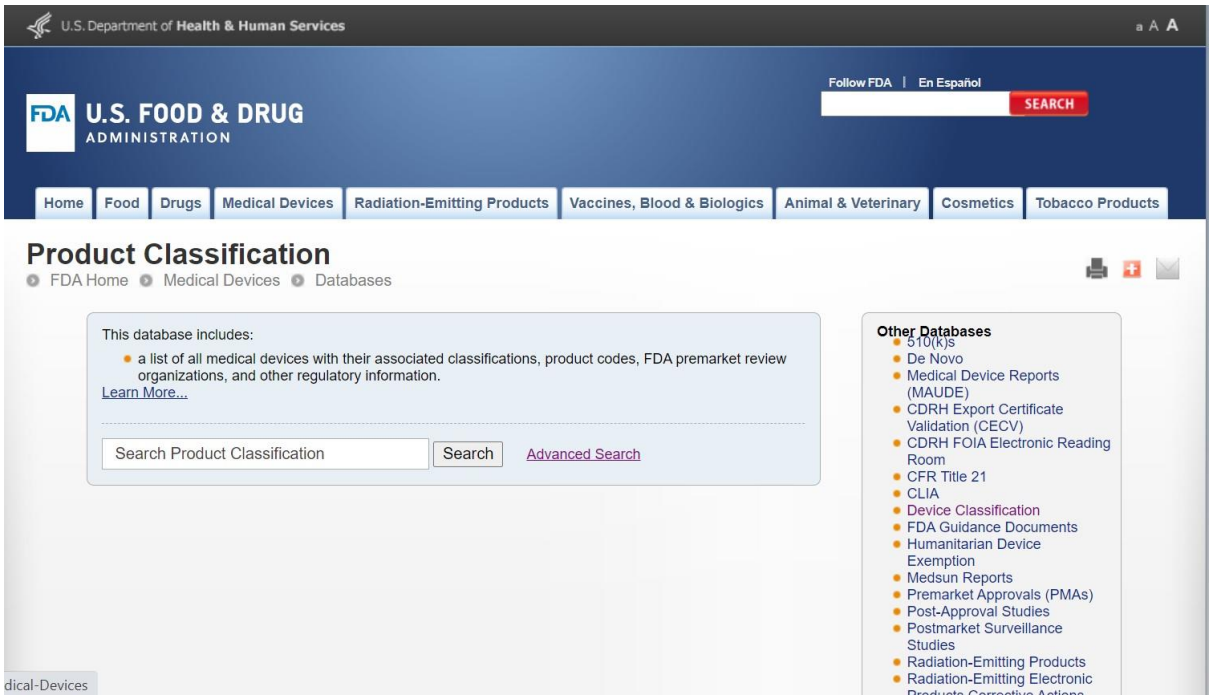
Most of the 510(k) approvals issued by the FDA can be downloaded from the FDA website. Other verification of medical device approval can be easily done by looking at the US FDA web page available at the following link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm and searching as per the information collected such as 510(k) number, name of the applicant.



By clicking on the search button, you will retrieve main information on the device in question if US FDA approved such as the following:

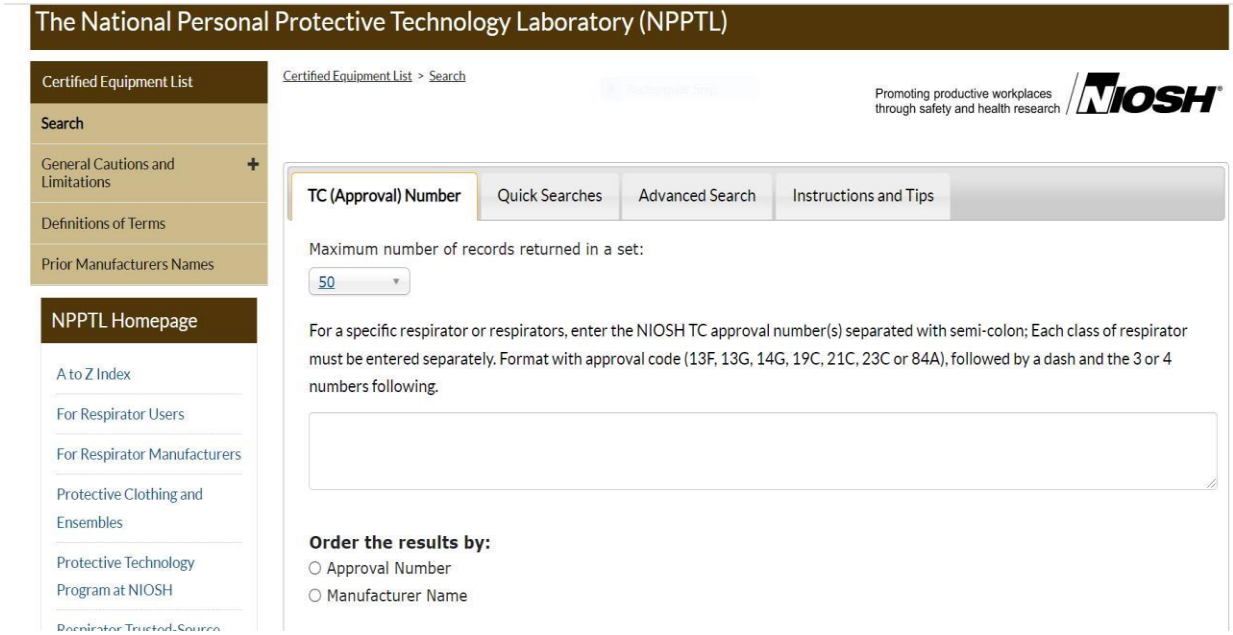


Clicking on summary link at the bottom of the box, will allow you to have access to the official notification letter from US FDA as well as the 510(k) summary which is the evidence of US FDA approval.



For respirators approved by NIOSH

NIOSH Certified Equipment List
https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html or
https://www2a.cdc.gov/drds/cel/cel_form_code.asp



For surgical respirators approved by USFDA and NIOSH

NIOSH surgical respirator list:
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html

Annex 11. Main critical parameters - Standards Comparison Tables

Table 1 : Particule Respirators EU versus US

	US-N95	EU-FFP2	EU-FFP3
Reference	NIOSH42CFR84	EN149:2001+A1:2009	EN149:2001+A1:2009
Assigned Protection factor	10	10	20
Particule Filtration Efficiency (%) – NaCl	≥95% (85 l/min)	≥94% (95 l/min)	≥99% (95 l/min)
Particule Filtration Efficiency (%) - Paraffin Oil	N/A	≥94% (95 l/min)	≥99% (95 l/min)
Total inward leakage (%)	N/A	≤8%	≤2%
Breathing resistance (Inhalation)	≤343 Pa (85 l/min)	≤240 Pa (95 l/min)	≤300 Pa (95 l/min)
Breathing Resistance (Exhalation)	≤245 Pa (85 l/min)	≤300 Pa (160 l/min)	≤300 Pa (160 l/min)
CO2 of inhalation air	N/A	≤1%	≤1%

Note: Other test can be applied based on suppliers ‘claims such as Penetration of Synthetic Blood

Table 2: Surgical Mask EU versus US

US - ASTM F2100	**Ref.**	Level 1	Level 2	Level 3
Bacterial Filtration Efficiency (%) – BFE	ASTM F2101	≥95%	≥98%	≥98%
Particulate Filtration Efficiency (%) - PFE	ASTM F2299	≥95%	≥98%	≥98%
Synthetic Blood	ASTM F1862	Pass at 80 mm Hg	Pass at 120 mm Hg	Pass at 160 mm Hg
Differential Pressure	EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2
Flame Spread	CFR16 Part 1610	Class 1	Class 1	Class 1

EU - EN 14683	**Sec.**	**Type I**	**Type II**	**Type IIR**
Bacterial Filtration Efficiency (%) – BFE	5.2.2	≥95%	≥98%	≥98%
Splash resistance (kPa)	5.2.4	Not required	Not required	≥ 16,0 kPa
Differential Pressure (Pa/cm2)	5.2.3	< 40 Pa/cm2	< 40 Pa/cm2	< 60 Pa/cm2
Microbial cleanliness (cfu/g)	5.2.5	≤ 30	≤ 30	≤ 30

Annex 12. Suggested approach for randomization