

IFC and BSI Launch Technical Benchmarking Guide for COVID-19-related PPE



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Introduction

The COVID-19 pandemic had a profound impact on the dynamics of global supply chains for personal protective equipment (PPE). It necessitated an urgent review and, in some cases, a temporary relaxation of the regulatory requirements and technical specifications in certain markets to ensure the ongoing availability of PPE for health care and front-line workers.

In parallel, on the supply side, many non-traditional manufacturers in various parts of the world ramped up their production capabilities, with some even manufacturing PPE for the first time, to help cope with demand. For those aiming to export their products, this means that they have to navigate their way through the many different market requirements around the world to ensure compliance with the relevant standards and technical regulations. These requirements are often similar but not identical, and specify varying test methods and conformity assessment procedures.

It was within this context that IFC (The International Finance Corporation; part of the World Bank Group) partnered with BSI (British Standards Institution) to develop a Technical Benchmarking Guide, with funding provided by the UK's Foreign, Commonwealth & Development Office. The guide is part of broader efforts by IFC and others to support global supply chains for PPE and to provide manufacturers and governments with a tool to expand the manufacturing and supply of PPE that is "fit for purpose", that adequately protects all healthcare workers and is produced without harming the environment.

The Technical Benchmarking Guide for COVID-19-related PPE

The benchmarking guide, launched in July 2022, presents the often complex and sometimes conflicting technical regulations, product standards and conformity assessment criteria in a simple way. It provides manufacturers and purchasers alike with a tool to navigate through the technical regulations, product specifications and conformity assessment requirements associated with 13 selected markets around the world. It is intended to help manufacturers identify the realities of potential new markets and to act as a starting point for them to delve deeper into the specific product requirements and test methods by consulting the relevant standards and technical regulations as necessary. It covers the products and markets shown in Figure 1.

Figure 1 – Products and markets covered by the Technical benchmarking Guide

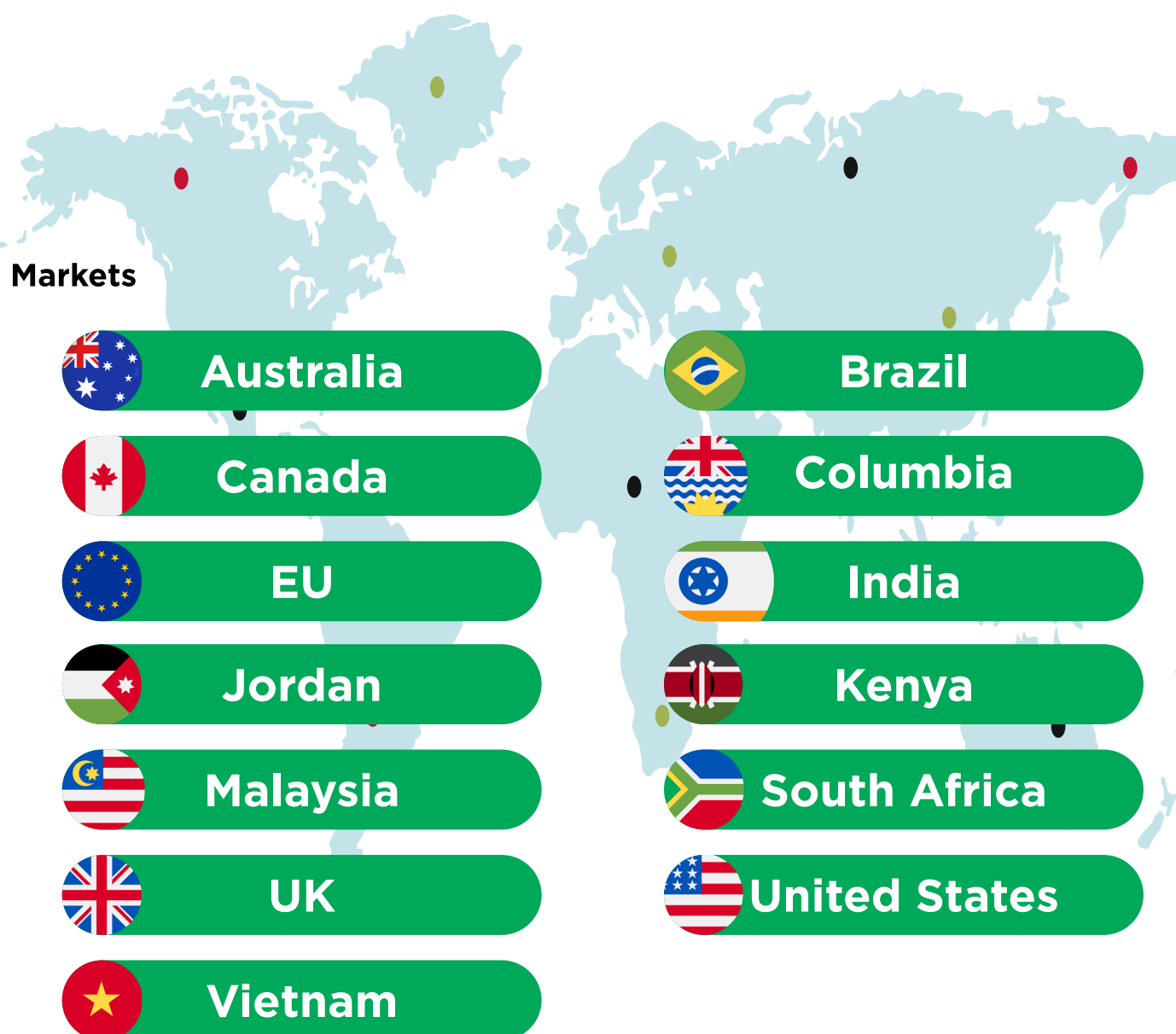
Products

Products

- **Masks**
 - Respirators
 - Medical face masks
 - Community face coverings
- **Eye and face protection**
 - Protective goggles/glasses
 - Face shields
- **Gloves**
 - Medical examination gloves
 - Surgical gloves
- **Clothing**
 - Full-body garments (including protective suits and coveralls) and partial-body garments (including aprons and shoe/head covers)
 - Gowns (including isolation and surgical gowns)

Markets

- Australia
- Brazil
- Canada
- Colombia
- EU
- India
- Jordan
- Kenya
- Malaysia
- South Africa
- UK
- United States
- Vietnam



Healthcare is the protection of mental and physical health by preventing or treating illness. A healthy person is not one with just the absence of disease, but health is a state of physical, mental, and social well-being. In general, healthcare is not practiced with this idea, modern healthcare facilities fix parts as if the person is a collection of mechanical systems. When one thinks about hospitals, what comes to mind is often a cold, sterile environment. Hospitals do not create inviting, healing spaces as people often encounter bad experiences, nervousness and grief in these spaces.

If the mind has the power to heal, fostering an environment that promotes mental wellness should translate to the physical healing of the body. Architecture has shown that the

Structure and Core Content of the Guide

The guide is split into sections from which the user can choose the relevant areas to access according to their needs:

- Part 1: Introduction and the technical criteria for the various PPE categories in selected markets
- Part 2: Generic descriptions of the main technical features for each PPE product category and associated standards for the selected markets
- Part 3: Market-specific information, including an overview of each market and generic information about the regulatory environment, approaches to standardization, and conformity assessment
- Part 4: Detailed comparisons of the technical requirements for the EU and US markets. International Organization for Standardization (ISO) product standards are also included where available
- Parts 5-15: Detailed fact sheets with comparisons (benchmarking) of the specific requirements for each product/market combination against the reference EU/US market requirements
- Annex A: Additional considerations for manufacturers and purchasers to take into account, including sustainability and diversity/inclusivity (gender) issues, and approaches to conformity assessment and accreditation.

The guide can be downloaded free of charge from the World Bank website:

<https://documents.worldbank.org/en/publication/documents-reports/document-detail/099048308082256583/idu0da7152d00e23f04d3f0a23f0cecec0a22344>

Simplifying a complex landscape

Overall, the guide seeks to simplify comparisons between the various COVID-19-related PPE categories and markets by using a system of colour coding to highlight similarities and differences. For those who need more detail, it also takes a deeper dive into the technical regulations, product standards, and testing criteria for each PPE/market combination. Making these comparisons is a complex process due to.

- The different regulatory approaches and relationships between (mandatory) technical regulations and (voluntary) standards used in different markets
- The different technical regulations associated with PPE and medical devices, with some
- PPE categories needing to meet one or both sets of regulations simultaneously
- International standards that are evolving quickly to cater to the needs of a rapidly changing PPE landscape but for which the latest versions are not always adopted at a national level or referred to in legislation. This time-lag in adoption can mean that the relevant standard might not be the latest version

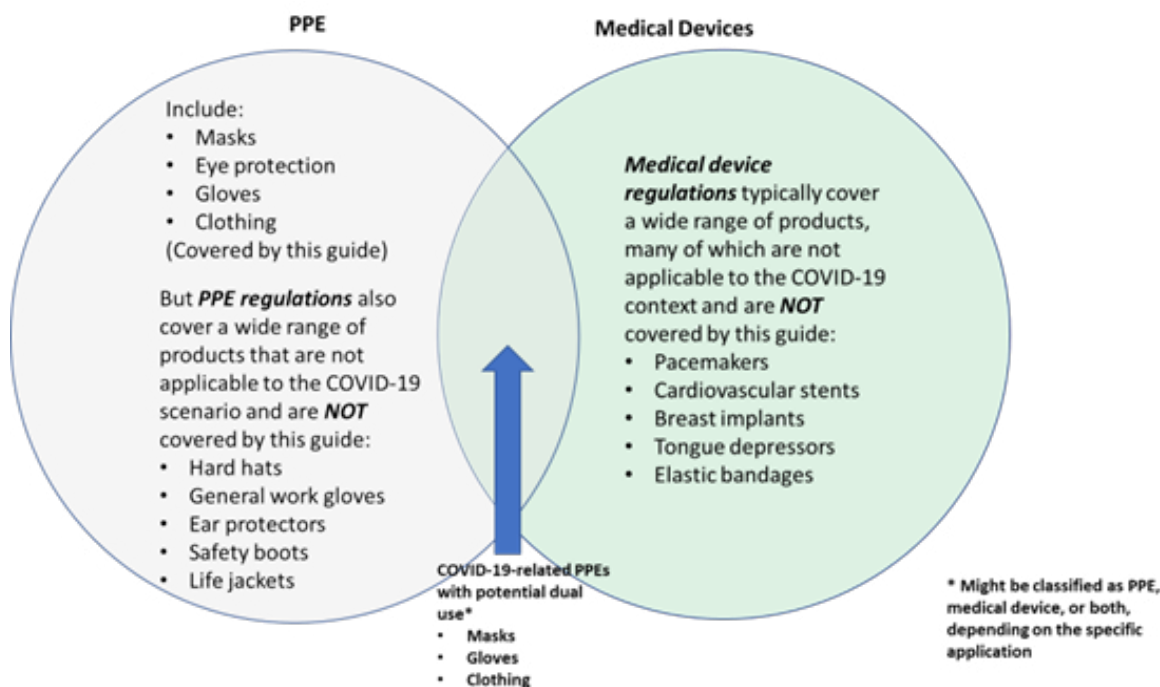
- The different testing methods that are required to demonstrate conformity to the various product standards. This can mean that although a specific category of PPE might be manufactured to meet the requirements of multiple markets, it has to undergo testing using different laboratory methods, approaches, or acceptance criteria. These are often expressed in different units of measurement, for which a direct comparison of results is impossible.

Standards and Technical Regulations

It is generally accepted good regulatory practice for technical regulations to specify “essential requirements” (usually based on generic performance criteria) while the technical details such as material performance characteristics, test methods, and so on are contained in (voluntary) standards. If a product conforms to the pertinent standard (called “harmonized standard” in the EU) then it is assumed that it fulfils the essential requirements in the technical regulations (“presumption of conformity” principle). This approach allows for technical progress to be accommodated through amendments or new editions of standards, while the technical regulation itself remains relatively stable. In some other situations, voluntary standards can become compulsory when directly referenced in the applicable regulations.

Typically, this means that regulations might refer to a wide range of PPE and medical devices, only some of which are relevant for COVID-19-related applications. This can be seen schematically in Figure 2.

Figure 2: Schematic representation of the interactions between PPE and medical devices



Comparison of standards used in the various markets covered by the guide

At a very high level, Figure 3 shows the basis for different countries’ standards for each category of PPE covered by the guide.

Figure 3 – Overview of the basis for national or regional standards in the various markets covered by the guide

■ Green: Based on or similar to ISO standard
■ Yellow: Based on or similar to EN standard
■ Blue: Based on or similar to a US standard
■ Red: Standalone national standard
 Blank: No applicable national standard

	n/a	3.1	3.2	3.3	3.4	3.5	3.6	3.7	3.8	3.9	3.10	3.11	3.12	3.13	Link to product details
	ISO	EU	United States	Australia	Brazil	Canada	Colombia	India	Jordan	Kenya	Malaysia	South Africa	UK	Vietnam	
Respirators	Green	Yellow	Blue	Red	Yellow	Red	Blue	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	2.1.1
Medical face masks	Green	Yellow	Blue	Red	Red	White	Blue	Red	Yellow	Yellow	Yellow	Blue	Yellow	Red	2.1.2
Community face coverings	Green	Yellow	Blue	White	Red	Red	Red	Red	Yellow	Red	White	White	Red	White	2.1.3
Face shields	Green	Yellow	Blue	Yellow	Blue	Red	Blue	Green	Yellow	Red	White	Red	Yellow	White	2.2.1
Protective goggles/glasses	Green	Yellow	Blue	Yellow	Blue	Red	Blue	Green	Yellow	Green	White	Red	Yellow	White	2.2.2
Medical examination gloves	Green	Yellow	Blue	Green	Green	White	Green	Red	Yellow	Green	Yellow	Green	Yellow	Green	2.3.1
Surgical gloves	Green	Yellow	Blue	Green	Green	White	Blue	Green	Yellow	Green	Yellow	Green	Yellow	Green	2.3.2
Suits and coveralls	Green	Yellow	Blue	Yellow	Red	White	Yellow	Red	Green	Red	Green	White	Green	Green	2.4.1.1
Aprons	Green	Yellow	Blue	Yellow	Red	White	Yellow	White	Green	Red	Green	White	Green	Green	2.4.1.2
Shoe and head covers	Green	Yellow	Blue	Yellow	Red	White	Red	White	Green	Red	Green	White	Green	Green	2.4.1.2
Gowns	Green	Yellow	Blue	Red	Yellow	Blue	Yellow	Red	Yellow	White	White	Yellow	Yellow	White	2.4.2

We can see from Figure 3, for example, that there is a predominance of EN-based standards for respirators, but for community face coverings there are only national or regional (“stand-alone”) standards. For PPE where ISO standards are available (such as surgical and medical examination gloves) these tend to be used as a basis for most national standards in the markets covered by the guide.

By using the two best-known markets - the European Union (EU) and the United States (US) - as reference points, the guide then goes into a deeper analysis of the differences and similarities between product standards used in each of the markets covered by the guide, and also makes detailed comparisons of the test methods that are referenced in those standards

Other important considerations

Circularity and Inclusivity

Although there is still a global paucity of standards and regulations related to sustainability, circularity, inclusivity and gender-related “fit” requirements for PPE, users of the guide are alerted to the need for these aspects to be taken into account, with further details being provided in Annex A of the guide.

In 2021 and 2022, for example, IFC put the spotlight on the need to move away from plastics-based, single-use, disposable PPE toward more sustainable PPE products and business models through IFC's publication "Innovation in Manufacturing Personal Protective Equipment—Toward Sustainability and Circularity."

In November 2021, IFC also convened stakeholders to discuss how PPE procurement and manufacturing can move away from "one size fits all" to cater to specific needs of female and male health care workers with a wider range of products and sizes that fit different body types. Both areas—sustainability and inclusivity/gender—are at the forefront of international attention and represent new opportunities for PPE production and procurement. Standards institutions and governments are expected to develop new technical standards and requirements in both areas.

Guidance for purchasers

In order for purchasers (governments, health care organizations, distributors of medical consumables and/or purchasing agents) to have confidence in the PPE they are buying, they need be aware of a number of factors, including criteria for supplier selection, how to specify requirements, verification of claims of conformity to quality management and/or product requirements and the importance of using accredited conformity assessment providers (for inspection, testing and certification, for example). These topics are explained in more detail by the Guide.

Webinars held to mark the Launch of the Technical Benchmarking Guide

In mid-2022, IFC and BSI held a series of international webinars to launch the guide (see

https://www.ifc.org/wps/wcm/connect/industry_ext_content/ifc_external_corporate_site/manufacturing/events/webinar_how+to+start+ppe+production

Webinar panelists featured representatives from international development organizations, standards bodies, government institutions, and manufacturers.

The main launch event, featuring high-level speakers from the UK, India, Brazil, USA, Greece and Jordan not only focused on the technical aspects of the PPE covered by the guide, but also brought a focus to diversity - specifically the need to design better-fitting PPE for women, and to the environmental challenges stemming from the widespread use of disposable PPE. "We must recognize that society's perception of 'quality' is rapidly expanding to embrace the impact that products, services, and processes have on wider society and the environment," said Lord Jamie Lindsay, President of the UK's Chartered Quality Institute.

The World Health Organization (WHO), which has worked on defining preferred characteristics for PPE and has prioritized the establishment of a global set of PPE standards, also presented at the event. WHO shares IFC's goal to promote better alignment of the various standards for PPE under a set of harmonized global standards that also address sustainability and gender considerations.

Periodic updates to the Guide

Because PPE standards and regulations continue to be revised and developed at the country and global level, IFC and BSI will update the guide periodically until December 2023. Nonetheless, while the guide will provide easy access to important information, the time lag involved in updating means that those working on PPE must always consult the most up-to-date versions of relevant standards and technical regulations.



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