



Technical Specification

ISO/TS 16766

Manufacturers' considerations for in vitro diagnostic medical devices in a public health emergency

*Aspects à prendre en compte par les fabricants de dispositifs
médicaux de diagnostic in vitro en situation d'urgence de santé
publique*

**First edition
2024-11**

Reference number
ISO/TS 16766:2024(en)

Full document details: ISO TS 16766-2024

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Published in Switzerland

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Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

During a pandemic, accurate identification and isolation of infected individuals is an effective initial response to secure public health and safety before vaccines are available. The coronavirus disease of 2019 (COVID-19) posed an unprecedented public health emergency, causing many countries to impose restrictions on travel and daily activities to slow the spread of infection. An example where the spread of COVID-19 infection was demonstrated to have been slowed before vaccines became available has been published.^[1] Here, a series of interventions, such as the urgent introduction of appropriate emergency use in vitro diagnostic (emergency use-IVD) medical devices, aggressive testing, rigorous contact tracing, etc., were applied in the early stage of the pandemic. Such a series of interventions effectively slowed the spread of infections and succeeded in maintaining public health and safety without the collapse of intensive care capabilities.

Often, regulatory authorization of in vitro diagnostic (IVD) medical devices takes months to a year or more to review and approve under a traditional regulatory pathway. Following a global infectious disease outbreak such as severe acute respiratory syndrome (SARS) or Middle East respiratory syndrome (MERS), the need for an accelerated regulatory pathway to facilitate the introduction of emergency use-IVD medical devices was recognised. While such pathways (i.e. emergency use authorization processes) have been implemented, the processes for authorization are neither well established nor harmonized.^[2-14]

While some international guidance is available for the minimum requirements for an IVD medical device in a public health emergency, the regulatory requirements can differ from one jurisdiction to another. For example, information on the quality system (e.g. ISO 13485), developmental history, or raw materials/manufacturing methods are required when a manufacturer applies for the accelerated regulatory pathway in some countries but not in others. Also, some countries require a stability shelf life claim, but the level of evidence required to demonstrate stability during the initial application varies by region.^[2,11,16,17] In an urgent situation such as a pandemic, the application of non-standardized requirements can impede implementation of the use of emergency use-IVD medical devices that are critical in protecting global public health.

This document provides minimum requirements, which span pre-market to post-market activities, to accelerate the availability of IVD medical devices in a public health emergency.

