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Electronic instructions for use for in vitro diagnostic medical devices — Minimum required information and means of delivery

Instructions électroniques d'utilisation des dispositifs médicaux de diagnostic in vitro — Informations minimales exigées et moyens d'administration

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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

Manufacturers of in vitro diagnostic medical devices (IVD), supply users with information to enable the safe use and the expected performance of their devices. The type and level of detail varies according to the intended uses and country-specific regulations.

The International Medical Device Regulators Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions can allow patients earlier access to new technologies and treatments. At the international level, the use of electronic instructions for use (eIFU) for different types of IVDs continues to expand which creates the need for a harmonized approach for eIFUs in the IVD sector.

IMDRF encourages manufacturers to employ the most appropriate methods of delivering information. Modern technologies enable instructions for use (IFU) and technical information to be provided using a more efficient means of delivery. Information can be digitally encoded on magnetic or appropriate storage media relevant with the state-of-the-art technologies, displayed on a screen, incorporated in the device, or even transmitted over the internet at the time of use. While these advances offer users the possibility of more timely availability of critical information, such as performance changes, and offer manufacturers more effective means of disseminating the information, a harmonised approach for a minimum required information and conditions for eIFU delivery (i.e. website availability, data security) is lacking thus far. In a fast-developing digital world a global standardization of eIFU requirements is crucial to promote their safe and effective use across the globe. Therefore, this document will help manufacturers, users and regulators to better align on and implement the minimum requirements and means of delivery for eIFUs.

This document provides a basis for harmonization of the requirements for electronic instructions for use for IVD medical devices. More specifically, this document covers the minimum required information to deliver and means of delivery for eIFUs for IVDs. Its focus is with the IFUs supplied with professional use, near-patient testing or point of care, and self-testing IVDs. The document entails the information on management of IFU revisions, risk assessment, website accessibility, data security, IFU accessibility and availability, and file format.

This document is intended to support the essential eIFU requirements of all the IMDRF partners, as well as other countries that have or plan to enact eIFU regulations for IVD medical devices. Users shall be aware of applicable regulations.

This document is not intended to be used alone. It contains terms and definitions used in the ISO 18113 series and in ISO 15223-1. Where synonyms are given, either term may be used but the first term is preferred. Some definitions had to be modified for relevance to IVD labelling or to conform to ISO terminology rules. In these cases, the source is given and indicates that the definition has been modified. In some cases, additional notes or modifications to existing notes were needed to clarify the application to IVD medical devices, and notes that did not apply to IVD medical devices were omitted.