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Needle-based injection systems for medical use — Requirements and test methods —

Part 7: Accessibility for persons with visual impairment

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 7: Accessibilité pour les personnes malvoyantes

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

— *Part 1: Needle-based injection systems*

— *Part 2: Needles*

— *Part 3: Finished containers*

— *Part 4: Needle-based injection systems containing electronics*

— *Part 5: Automated functions*

— *Part 6: On-body delivery systems*

— *Part 7: Accessibility for persons with visual impairment*

Introduction

Prior to this part of ISO 11608, the ISO 11608 series has not provided guidance to address the use of NIS by persons with visual impairment. The reality, however, is that a significant number of NIS users have visual impairments and operate these devices, even though the user interfaces rely primarily on visual communication to provide the information needed for safe and effective use. The result is that users with visual impairment have difficulty and may be at greater risk when using these products.

Given the prevalence of visual impairment and the fact that many NIS target disease states (e.g. diabetes) with co-morbid conditions that can impair vision, efforts should be made to eliminate or minimize, where possible, device features that constitute obstructions to product use for users with visual impairment.

This part of ISO 11608 defines terms related to visual impairment and provides guidance to enable manufacturers to provide information to the user in other sensory formats (e.g. tactile, auditory). New and existing features that address the needs of users with visual impairment will also benefit a broader population.

The purpose of this part of ISO 11608 is to assist manufacturers in developing NIS designs that will be usable for users with visual impairment but recognizes that those designs could be more usable also for users with no visual impairment. Taking this type of "universal design"[29] approach is preferable to the creation of "niche" products only for users with visual impairment, for which the market would be smaller and, consequently, the product cost likely would be higher. Applying universal design principles to extend access to users with visual impairment can increase the market size, thereby reducing product cost and enabling a broader patient population to access the NIS.

For product design purposes, it should be assumed that some users will have moderate visual impairment but will be able to read large print and see high-contrast product features. Other users, however, will not be able to make use of any visual features and will instead require information to be provided through other sensory means (e.g. tactile or auditory). Therefore, this part of ISO 11608 includes the requirement to provide information in visual formats that can be perceived and understood by people with moderate visual impairment and in non-visual formats (e.g. tactile or auditory) that can be perceived and understood by people with no useful vision.

In conjunction with other parts of the ISO 11608 series, manufacturers are expected to follow a risk-based approach and employ human factors engineering during the design, development, and manufacture of NIS serving this important user population. Existing products and those currently under development may not fulfil some of the requirements given by this part of ISO 11608. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain a higher level of accessibility.

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.