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Use and handling of medical devices covered by the scope of ISO/TC 84 — Risk assessment on mucocutaneous blood exposure

Utilisation et manipulation des dispositifs médicaux couverts par le domaine d'application du ISO/TC 84 — Évaluation du risque concernant l'exposition au sang mucocutané

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

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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.

ISO/PAS 18761 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters.*

Introduction

Use and handling of medical devices covered by ISO/TC 84 might expose mucocutaneous membranes to blood or bodily fluids. Although exposure of mucous membranes to blood and bodily fluids may present a risk for infection, the pathogenesis is unknown. This exposure risk is to be included in the risk assessment taking into account that the exposure should be minimized as far as possible.

Use and handling of medical devices covered by the scope of ISO/TC 84 — Risk assessment on mucocutaneous blood exposure

1 Scope

This Publicly Available Specification covers requirements for risk assessment on mucocutaneous blood and bodily fluid exposure in relation to the handling of medical devices for the administration of medicinal products covered by the scope of ISO/TC 84.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 General requirements

The risks in relation to the possible exposure of mucous membranes to blood and bodily fluids from the medical device shall be assessed in accordance with the risk assessment specified in ISO 14971, as exposure of those membranes to these fluids might pose a risk of infection.

The output of the risk assessment shall be part of the input into the development of new devices, including possible complementary personal protective equipment, and labelling (including marking, sales and education materials) in order to minimize the risk of infection due to exposure of mucous membranes, specifically eyes, mouth and nose, to blood and bodily fluids.

4 Information and educational materials provided by suppliers

The device shall be accompanied by sufficient information to use it safely in relation to the possible exposure of mucous membranes to blood and bodily fluids from the medical device, taking into account the training and knowledge of the potential users.

Where needed on the basis of the risk assessment, the information shall contain the following particulars:

— any warnings in relation to the risks associated with the possible exposure of mucous membranes to blood and bodily fluids from the medical device;

— any precautions to be taken in relation to the possible exposure of mucous membranes to blood and bodily fluids from the medical device.

Further recommendations and useful information to minimize the risk of infection due to exposure of mucous membranes (e.g. possible recommendations in relation to the use of personal protective equipment during handling of the device) can be provided by various means, such as training and educational documentation, sales materials, websites and other types of media.

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