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Medical devices - Application of risk management to medical devices

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 Directives for

Standardization - Part 1.Rules for the Structure and Drafting of Standardizing Documents.

This Document equivalently adopts ISO 14971.2019 Medical Devices - Application of Risk

Management to Medical Devices.

Please note some contents of this Document may involve patents. The issuing agency of this

Document shall not assume the responsibility to identify these patents.

This Document was proposed by National Medical Products Administration.

This Document shall be under the jurisdiction of National Technical Committee on Quality

Management and General Requirements for Medical Device of Standardization Administration

of China (SAC/TC 221).

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1 Scope

This document specifies terminology, principles and a process for risk management of medical

devices, including software as a medical device and in vitro diagnostic medical devices. The

process described in this document intends to assist manufacturers of medical devices to

identify the hazards associated with the medical device, to estimate and evaluate the associated

risks, to control these risks, and to monitor the effectiveness of the controls.

2 Normative References

There are no normative references in this Document.

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following

addresses.

4 General Requirements for Risk Management System

Top management shall provide evidence of its commitment to the risk management process by

ensuring.

Risk management activities shall be planned. For the particular medical device being

considered, the manufacturer shall establish and document a risk management plan in

accordance with the risk management process. The risk management plan shall be part of the

risk management file.

5 Risk Analysis

The manufacturer shall document the intended use of the particular medical device being

considered.

For the particular medical device being considered, the manufacturer shall identify and document those qualitative and quantitative characteristics that could affect the safety of the medical device. Where appropriate, the manufacturer shall define limits of those characteristics.

6 Risk Evaluation

For each identified hazardous situation, the manufacturer shall evaluate the estimated risks and determine if the risk is acceptable or not, using the criteria for risk acceptability defined in the risk management plan.

7 Risk Control

The manufacturer shall implement the risk control measures selected in 7.1.

Implementation of each risk control measure shall be verified. This verification shall be recorded in the risk management file.

8 Evaluation of Overall Residual Risk

After all risk control measures have been implemented and verified, the manufacturer shall evaluate the overall residual risk posed by the medical device, taking into account the contributions of all residual risks, in relation to the benefits of the intended use, using the method and the criteria for acceptability of the overall residual risk defined in the risk management plan [see 4.4 e)].

9 Risk Management Review

Prior to release for commercial distribution of the medical device, the manufacturer shall review the execution of the risk management plan. This review shall at least ensure that.

10 Production and Post-Production Activities

The manufacturer shall review the information collected for possible relevance to safety,