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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 1474-2016 / IEC 62366:2007

Medical Devices - Application of Usability Engineering to Medical Devices

医疗器械 可用性工程对医疗器械的应用

(IEC 62366:2007, IDT)

Issued on: January 26, 2016 **Implemented on: January 01, 2017**

Issued by: China Food and Drug Administration

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Foreword

This Standard was drafted as per the rules specified in GB/T 1.1-2009.

This Standard used the translation method to equivalently adopt IEC 62366:2007 *Medical Devices – Application of Usability Engineering to Medical Devices*.

Terms are shown in bold in this Standard.

The clauses and articles with an asterisk (*) in this Standard have explanations on their reasons in Annex A.

Please note some contents of this Document may involve patents. The issuing agency of this Document does not assume the responsibility to identify these patents.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of Management Centre of the Standards for Medical Devices, China Food and Drug Administration.

Drafting organizations of this Standard: Beijing Hua Guang Certification of Medical Devices Co., Ltd.; and Shanghai Testing & Inspection Institute for Medical Devices.

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Medical Devices - Application of Usability Engineering to Medical Devices

1* Scope

This Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to SAFETY of a MEDICAL DEVICE. This USABILITY ENGINEERING PROCESS assesses and mitigates RISKS caused by USABILITY problems associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

NOTE: For the purposes of this standard, USABILITY (see 3.17) is limited to characteristics of the USER INTERFACE.

If the USABILITY ENGINEERING PROCESS detailed in this Standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of a MEDICAL DEVICE are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2).

This Standard does not apply to clinical decision-making relating to the use of a MEDICAL DEVICE.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this document.

NOTE: Informative references are listed in the “Bibliography”.

YY/T 0316-2016 Medical Devices – Application of Risk Management to Medical Devices (ISO 14971:2007 revised edition, IDT)

3 Terms and Definitions

For the purpose of this document, the terms and definitions given in YY/T 0316-2016 and the following apply.

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