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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国国家标准

GB/T 19634-2005

In vitro diagnostic test systems - General technical requirements for blood-glucose monitoring systems for self-testing

体外诊断检验系统 自测用血糖监测系统通用技术条件

(ISO 15197:2003, NEQ)

Issued on January 24, 2005 Implemented on May 1, 2005

Issued by General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

Standardization Administration of the People's Republic of China

Contents

Foreword

GB/T 19634 *In vitro diagnostic test systems - General technical requirements for blood-glucose monitoring systems for self-testing* is not equivalent to ISO 15197.

This Standard is proposed by National Food and Drug Administration

This Standard is centralized by National Clinical testing laboratory and National Technical Committee of Standardization for in vitro diagnostic test systems.

This Standard is drafted by: Beijing Institute of Medical Device Testing and Johnson&Johnson.

Main drafters of this Standardization: Hu Dongmei, Xu Yong, John Mahoney.

Introduction

Blood-glucose monitoring systems are in vitro diagnostic medical devices used predominantly by laypersons affected by diabetes mellitus. When used properly, a glucose monitoring system allows the individuals to monitor and take action to control the concentration of glucose present in the blood.

The primary objectives of this Standard are to establish requirements that result in acceptable performance on the premise that laypersons accept certain training, devices are properly maintained and operated in accordance with the calibration and quality control procedures in instructions and to specify procedures for demonstrating conformance to this Standard.

This Standard demonstrates general technical requirements for blood-glucose monitoring systems for self-testing, including the information supplied by the manufacturer and labels and instructions on blood-glucose monitoring systems for self-testing. Since this self-testing systems are used by laypersons, the information supplied by the manufacturer shall be explicit and easily to be understood for the convenience of correct self-testing. Certain warnings or prompts shall also be supplied to guide the appropriate measures under abnormal results. The content of information supplied by the manufacturer are addressed in this Standard.

In vitro diagnostic test systems—

General technical requirements for blood-glucose monitoring systems for self-testing

1 Scope

This Standard stipulates the terms and definitions, requirements, test methods, labels and instructions, package, transportation and storage for blood-glucose monitoring systems for self-testing.

This Standard is applicable to the blood-glucose monitoring systems for self-testing intended for in vitro monitoring the concentration of glucose present in capillary whole blood and/or venous whole blood (normally including portable glucose meters, disposable test strips and control materials).

2 Normative references

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB 4793.1-1995 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (idt IEC1010-1:1990)

GB 9706.1-1995 Medical electrical equipment – Part 1: General requirements for safety (idt IEC 601-1:1988)

GB/T 14710-1993 Environmental requirements and testing methods for medical electrical equipment

YY 0466-2003 Medical electrical equipment – Symbols for electrical equipment for label, mark and providing information (ISO 15223:2000, IDT)

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