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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Electronics and Information Technology Industries Association (JEITA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 0601-1** : 1999 has been revised and replaced with this Standard.

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Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

Introduction

This Japanese Industrial Standard has been prepared based on the third edition of **IEC 60601-1** published in 2005 with some modifications of the technical contents in order to reflect the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with explanations is given in Annex JC.

As for the portions with an asterisk (*) in clauses and subclauses, etc. of this Standard, the explanation of the grounds are given in Annex A.

In this Standard, the capital letters in the text mean terms defined in clause 3 of this Standard. If not indicated in capital letters, the terms defined in the Standard mentioned above are interpreted in context without applying the definition.

1 Scope, object and related standards

1.1 * Scope

This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, (hereafter referred to as ME EQUIPMENT and ME SYSTEMS).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this Standard are not covered by specific requirements in this Standard except in **7.2.13** and **8.4.1**.

NOTE 1 See also **4.2**.

This Standard can also be applied to equipment used for compensation or alleviation of disease, injury or disability.

In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT is covered by the **IEC 61010** series. This Standard does not apply to the implantable parts of active implantable medical devices covered by the **ISO 14708-1** series.

NOTE 2 The International Standards corresponding to this Standard and the symbol of degree of correspondence are as follows.

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