# MEET THE EXPERTS FOR MEDICAL DEVICE SAFETY

ACCORDING TO

# IEC 60601-1:2005 – 3RD EDITION

MEDICAL TESTING AND CERTIFICATION SERVICES FOR GLOBAL MARKETS

CSA Group

## DO YOU NEED A TRANSFER TO THE 3RD EDITION OF THE IEC 60601-1:2005 STANDARD?

CSA Group is a leading provider of product testing and certification services and the widely recognized CSA mark for the North American and global market.

CSA Group's highly qualified experts have in-depth knowledge of the IEC 60601-1 standard's 2nd and 3rd edition and will guide and support you throughout the entire process.

## IEC 60601-1:2005 – 3RD EDITION

IEC 60601-1 is a basic standard for medical electrical equipment recognized by public health authorities in most countries. Its 3rd edition was first published in 2005 and covers general requirements in regards to basic safety. The new edition complements the 2nd by incorporating the risk management process and asking for essential performances.

The IEC standard is used for the CB Scheme and recommendable for other conformity procedures such as MDD (Medical Device Directive) for CE marking.

Our services – your advantages:

- Access to over 70 countries
- Expertise in the 2nd and 3rd edition of the IEC 60601-1:2005 standard
- Ease in obtaining dual certification (2nd and 3rd edition)
- Guidance for supporting documents such as risk management files and defining essential performances
- Cost savings through simplified acceptance
- Time saving through an expedited process

## CB SCHEME

The CB Scheme is an international program for the mutual recognition of product safety test results among participating laboratories and certification organizations around the world. It enables manufacturers to obtain multiple national safety certifications for their products.

It was established by the IEC (International Electrotechnical Commission) in order to facilitate international trade. As a leading medical National Certification Body (NCB), CSA can issue a CB test report and certificate based on the test results.

**Transition Plan:**

- Incorporating risk management
- Fulfilling MOPP (Means of Patient Protection)/ MOOP (Means of Operator Protection) requirements
- Defining essential performances
- Adhering to effective dates

**Transition Dates:**

| | |
|---|---|
| European Union general standard | June 1, 2012 |
| European Union particular standards | various* |
| Canada general standard | June 1, 2012 |
| Canada particular standards | various* |
| USA (FDA) | July 1, 2013 |
| Brazil | January 1, 2014 |
| Other countries | tbd |

* Particular standards for medical equipment are subject to various dates (see Official Journal of the EU). A transition period of 3 years starting from the date of publication of that particular standard is valid for the EU and Canada.

## CSA GROUP

With more than 90 years of experience, CSA Group is a leading certification organization in the USA and Canada. The American National Standards Institute (ANSI), the Occupational Safety and Health Administration (OSHA) and the Standards Council of Canada (SCC) have accredited CSA Group as an official testing and certification body. CSA Group is also a member and national CB Scheme certification body of the IEC System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE).

Contact us for further information. Our expert team will assist you with all questions regarding testing and certification according to the 3rd edition of the IEC 60601-1:2005 standard.

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