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EN 61010 3rd Edition will be mandatory for products needing to comply with the EU low voltage directive for CE marking. The CB Scheme accepted IEC 61010-1 in August 2010. In North America, UL announced the effective date for 61010-1 third edition is January 1, 2018.

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aimed to extend the scope of application to all overseas subsidiaries of the TOK Group. As we move forward with globalization of our business activities in recent years the TOK Group has grown and now consists of people from many countries or regions around the world.

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Conduct 3rd Edition

Your new and existing medical devices must demonstrate compliance with the latest revision of IEC 60601. We are a Nationally Recognized Testing Laboratory (NRTL) approved by OSHA , providing testing, certification, and in-lab support to help you navigate the new requirements of the 3 rd Edition of IEC

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60601 and to support your safety claims throughout North America and Europe.

IEC 60601: Product Safety Standards for Medical Devices

In 2005, the third edition of IEC 60601-1 was published. It was the result of a comprehensive review of the second edition (dating from 1988). Some key

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changes are: the outline and the numbering scheme of the clauses and subclauses were changed, risk management was made much more relevant and the concept of essential performance was added.

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Japan compliance to the 2nd edition standard was withdrawn from May 31, 2017 at which time 3rd edition became effective, although from March 1, 2019

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this must be to IEC 60601-1:2005 with Amendment 1 (also referred to as Edition 3.1).

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