



VALUE OF INTERNATIONAL STANDARDS FOR CONFORMITY ASSESSMENT

UL | Empowering Trust in a Complex World

WHO BENEFITS?

- Consumer
- Manufacturer
- Regulator
- Government
- Retailer



ADVANTAGES

- Safety
- Time to Market
- Cost Savings
- Uniform Requirements / Consistency
- Quality
- Market Entry Simplified
- Collaboration
- Cooperation
- One-stop-shop



CHALLENGES

- Timing of acceptance in different geographies
- National differences
- Standards change
- Covering many regions
- Covering everything for a particular region
- Test variations, additions
- No guarantee of regulatory acceptance
- Intended regions unknown



IEC 60601-1 ACCEPTANCE DATES

IEC 60601-1 implementation timelines for medical devices

Country	IEC 60601-1 edition 3	IEC 60601-1 edition 3.1
Brazil	Not accepted	Required
Canada	Required but 3.1 accepted	Accepted
China*	Not accepted	Not accepted (estimated by 2019)
Europe	Accepted until 31 DECEMBER 2017	Required 1 JANUARY 2018
India	Required but 3.1 accepted	Accepted
Japan	Accepted until 30 JUNE 2019	Required 1 JULY 2020
South Korea	Required but 3.1 accepted	Accepted
Singapore*	Accepted	Accepted
Taiwan	Required but 3.1 accepted	Required 30 JUNE 2019
United States	Not accepted	Required

* IEC 60601-1 edition 2 is accepted in Singapore and China.

Data in chart accurate as of September 2017, additional details at www.ul.com/medical-and-laboratory/medical-devices/ul-60601



HOW ARE STANDARDS APPLIED IN CONFORMITY ASSESSMENT?

- Intended geographies must be known
- Application of standards varies based on region
- Standard editions accepted may vary
- National or local differences
- Regulator requirements
- Power system differences
- Standardized test reports
- CB Scheme



INTERNATIONAL VS NATIONAL REQUIREMENTS

- National may include additional specific requirements
- International exclude detailed local requirements
- Published national differences
- Unpublished local or regulatory differences
- National may allow waiving of standards
- Local Mark requirements
- International cover most, national fill in gaps



SUMMARY & EXAMPLES OF PROGRESS

- UL Participation
 - IEC committees
 - Standards development
 - Public safety mission
- Interaction & participation
- New technologies
- Goal to benefit all stakeholders

