



Choose certainty.  
Add value.

## TÜV SÜD

Solutions that ensure quality, safety  
and sustainability for future  
generations

# Stouffville Site



- EMC Testing IEC 60601-1-2
- Product Safety IEC 60601-1
- Radio testing to international standards
- Environmental
- Laser / LED
- HALT
- Free product review if you come to our facility

# Do's and Don'ts of certification and testing



- Meant to get you to market faster and to save testing costs.
- Based on experience and client feedback

# Do consider Risk Management ISO 14971



- Called out by IEC 60601-1
- Accepted worldwide
- Should help not hinder product design
- Is required before a lab starts testing
- Should be considered a process during product development
- Helps you design a device that will comply
- Be ready to change the product as you go along

# Don't skip pre-scans/ construction review



- Pre-scans commonly done on Radiated Emissions and Immunity
- affordable
- Let you know potential issues early on
- Helps you design a device that will comply
- Construction review will address documentation as well as design

# Do Ensure components are pre approved



- NRTL marks required for sale in North America
- Look into Radio certifications for the markets you want to sell to
- Look out for fake marks
- Don't take a suppliers word, ask for accredited test reports
- For Lithium Batteries IEC 62133 is accepted worldwide



# Research and know your standards early on



- IEC 60601-1-2 4<sup>th</sup> ed for EMC
- IEC 60601-1 3<sup>rd</sup> ed for Safety
- Is home use applicable? IEC 60601-1-11:2015
- Any -2 collateral standards? IEC 60601-2-47 ECG, EN 60601-2-37 Ultrasonic equipment
- Get standards in writing from Health Canada / FDA

# Don't engage with a test lab too late



- Schedule testing a few weeks in advance of needing it
- Set testing expectations early on
- Be responsive to engineers feedback





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**One-stop quality, safety,  
and sustainability  
solutions.**

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