Security by Design Confidence



- In December 2019, Underwriters Laboratories (UL) launched a new security option for their IEC 62304 Registered Firm certification program.
- This new option is designed to evaluate the internal capability maturity of a medical device manufacturer (MDM) to test the robustness of their products' security controls, using the tests of UL 2900-2-1 Software Cybersecurity as part of their IEC 62304 Medical Device Software Life Cycle Processes.
- Philips is the first MDM to exercise this new option for demonstrating their internal security testing capability maturity.

IEC 62304 Clause 7.3, verification of risk control measures using the specific security requirements of Clauses 13-19 of the Standard for Software Cybersecurity for Network-Connectable Products, Parts 2-1: Particular Requirements for Network Connectable Components for Healthcare and Wellness Systems, UL 2900-2-1





Security by Design Confidence



Philips Security Center of Excellence (SCoE) for the management of cybersecurity testing of medical devices is certified by Underwriters Laboratories (UL)

- ✓ Laboratory quality management system,
- ✓ Security Risk Management
- ✓ Software Security Verification Planning
- ✓ Change Management / Continuous Improvement
- ✓ Verification of Security Risk Control Measures

IEC 62304 Clause 7.3, verification of risk control measures using the specific security requirements of Clauses 13-19 of the Standard for Software Cybersecurity for Network-Connectable Products, Parts 2-1: Particular Requirements for Network Connectable Components for Healthcare and Wellness Systems, UL 2900-2-1



Security by Design Confidence

Philips Security Center of Excellence (SCoE) – Underwriters Laboratories (UL) certification covers specific UL 2900-2-1 Medical device testing for....

- ✓ Known Vulnerability Testing
- ✓ Malware Testing
- ✓ Malformed Input Testing
- ✓ Structured Penetration Testing
- ✓ Software Weakness Analysis
- ✓ Static Source Code Analysis
- ✓ Static Binary and Bytecode Analysis

IEC 62304 Clause 7.3, verification of risk control measures using the specific security requirements of Clauses 13-19 of the Standard for Software Cybersecurity for Network-Connectable Products, Parts 2-1: Particular Requirements for Network Connectable Components for Healthcare and Wellness Systems, UL 2900-2-1

