

MEDICAL DEVICE SECURITY TESTING AND CERTIFICATION



The healthcare industry is one of the most critical infrastructures in each country. Patients deserve the best possible medical support, which motivates and triggers the fast-paced dynamics of the industry. Security is often an invisible aspect for the end user, as the attention falls on the performance of a medical device or a service. Secura is actively involved in the domain of medical devices security, and up to date with the developments concerning standards, regulations and certifications.






IN CONTROL WITH SECURA

Secura has worked in information security and privacy for nearly two decades. This is why we uniquely understand the challenges that you face like no one else and would be delighted to help you address your information security matters efficiently and thoroughly. We work in the areas of people, processes and technology. For our customers we offer a range of security assessment services varying in depth and scope.

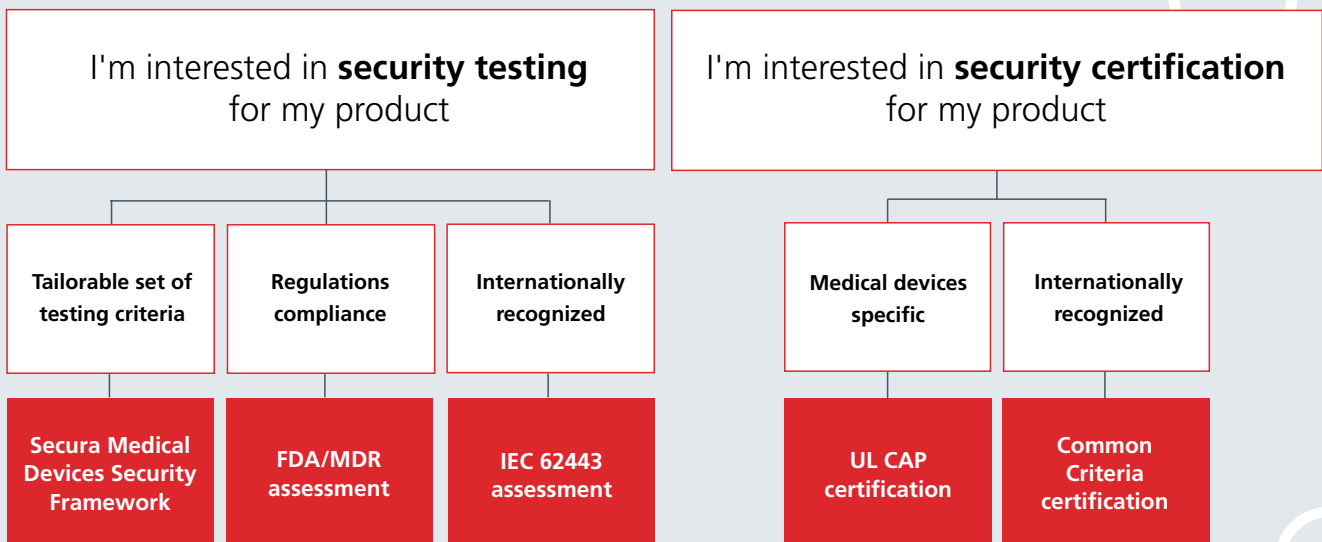
Medical devices are among the highest risk connected components, due to their direct impact to the health of humans. Several years ago, medical devices, including the medical systems placed within hospitals, were operated mostly offline, not leaving much room for possible cybersecurity threats. Nowadays, the advantages of (Internet) connected infrastructures can be seen also in the way in which both complex medical systems (e.g. complex MRI scanners), as well as personal medical devices (e.g. insulin pumps) communicate with each other. The moment when these devices and systems are connected using their interfaces, this opens the doors to relevant cybersecurity threats.



Testing and Certification for Medical Devices

Testing		Certification	
<p>Secura Medical Devices Security Framework</p> 	<p>Tailorable assessment focused on state of the art standards (UL 2900, IEC 62443, FDA security guidelines).</p>	<p>UL CAP</p> 	<p>Recognized certification demonstrating the compliance necessary to enter the USA market (FDA security requirements).</p>
<p>FDA/MDR Compliance</p> 	<p>Security assessment focused on providing compliance evidence for the FDA and MDR regulations.</p>	<p>Common Criteria</p> 	<p>Internationally recognized security certification scheme, covering all types of IT products.</p>
<p>IEC 62443</p> 	<p>Security assessment based on internationally recognized standard, applicable to medical devices.</p>		

Which Service Do You Need?



Testing Services

SECURA MEDICAL DEVICES SECURITY FRAMEWORK

- ▶ Proprietary IoT security assessment framework, developed by combining relevant requirements from several state-of-the-art publications and standards, such as IEC 62443, UL 2900 and ENISA baseline security requirements.
- ▶ Allows customers to tailor the evaluation criteria, focusing specifically on certain security topics, requirements or points of interest.

FDA/MDR COMPLIANCE

- ▶ Tailored service in line with the compliance requirements of the FDA regulation (valid for USA) or the MDR regulation (valid for EU).
- ▶ Assessment including a combination of documentation review, validation testing on the product and penetration testing for demonstrated robustness.

IEC 62443 COMPLIANCE

- ▶ Recognized standard for the assessment and validation of medical devices.
- ▶ Offers possibilities for the assessment of simple medical devices (IEC 62443-4-2) as well as complex medical systems (IEC 62443-3-3).
- ▶ Assessment focused on the validation of security capabilities (e.g. authentication, role separation, interface protection, logging, etc.) implemented in the medical devices and systems.

Certification Services

UL CAP CERTIFICATION

- ▶ Certification scheme operated on top of UL 2900 standard.
- ▶ Recognized certificate for demonstrating compliance with FDA security requirements (USA market clearance).

COMMON CRITERIA CERTIFICATION

- ▶ International certification scheme, offering significant visibility and market recognition.
- ▶ Recognition of certificates under EU, USA, Australia, UK, Asia, etc.
- ▶ Various levels of certification possible.

Would you like to know more about security testing and/or certifying your medical device?

Contact us today to discuss our services in more detail and find out which service fits your product best.



Interested?

Would you like to learn more about our services? Contact us today:

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