To deliver better patient care, medical devices and systems are becoming more connected and capable. This also means they are becoming increasingly more susceptible to malicious attacks. Organizations need real solutions to help identify security risk, balance that risk with usability and availability, and achieve regulatory approval.

Medical device security expertise

Whether you need to test one medical device quickly, identify the risks in a complex system of devices and applications, or establish a secure development process, our experts can help ‘Build Security In’ to your development process through services such as threat modeling, architecture risk analysis, static application security testing (SAST), and penetration testing.

Our assessment experience includes a broad range of medical and non-medical embedded systems including implanted medical devices, drug delivery systems, surgical imaging systems, ATMs, gaming consoles, and smart meters. When working with us, you are benefiting from the innovations of multiple industries.

HIPAA Security Rule regulations

If you’re in the healthcare industry, we can help you meet the software security-related regulations set by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to establish the privacy and breach notification rules for healthcare data. We’ll help you address HIPAA’s Security Rule which requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information (e-PHI).
Software Security Initiative-in-a-Box (SSIB) for Healthcare

If your organization is subject to the HIPAA Security Rule and you create or sell software, or purchase and deploy software internally, you need a software security initiative (SSI) to protect your business. There are specific elements of the HIPAA Security Rule that your software development organization need to consider:

- The ‘safe harbor’ exemption in the HIPAA Security Rule relieves a data owner of onerous government requirements for public notification and fines when a breach occurs, if the data is properly encrypted.
- Specific requirements for protecting healthcare data that is stored in a cloud or data warehouse environment.
- Your applications’ ability to singularly identify the person who has access to healthcare data.
- Audit logs must be kept for a longer period of time than is typical for most applications.

Our SSIB for Healthcare gives a software development organization a quick start towards meeting the constraints of the HIPAA Security Rule as it applies to software architecture, design, development, and testing.

Waiting to start your SSI means more security defects getting into production software, more compliance failures, and increased business risk. It also increases the time attackers have to exploit these issues.

We have our finger on the pulse

We are actively involved in medical and healthcare industry efforts to help clients build more secure care-delivery systems. Our team collaboratively creates secure design guidance documents through the Association for the Advancement of Medical Instrumentation (AAMI) working groups, including IEEE’s Avoiding The Top 10 Software Security Design Flaws and IEEE’s Building Code for Medical Device Software Security. We’ve also worked with the Archimedes Group at the University of Michigan, Institute of Electrical and Electronics Engineers (IEEE), National Science Foundation (NSF), National Health ISAC, and Food and Drug Administration (FDA) to help healthcare companies combat cyber criminals.

The Synopsys Difference

Synopsys offers the most comprehensive solution for integrating security and quality into your SDLC and supply chain. Whether you’re well-versed in software security or just starting out, we provide the tools you need to ensure the integrity of the applications that power your business. Our holistic approach to software security combines best-in-breed products, industry-leading experts, and a broad portfolio of managed and professional services that work together to improve the accuracy of findings, speed up the delivery of results, and provide solutions for addressing unique application security challenges. We don’t stop when the test is over. Our experts also provide remediation guidance, program design services, and training that empower you to build and maintain secure software.

For more information go to www.synopsys.com/software.