Safety, Security & Privacy Compliance

Corsano Health develops, produces and markets safe, secure, and reliable medical devices based on our expertise and compliance with the following regulatory standards:

ISO 9001 Quality Management

International standard for a quality management system to provide products and services that meet customer and regulatory requirements and to demonstrate continuous improvement

ISO 13485 Medical Devices – Quality Management

Quality management system requirements necessary to provide medical devices and highest quality, meeting customer requirements and complying with medical regulations

ISO 27001 Information Security Management

Information security management standard necessary to provide the highest levels of confidentiality, integrity, and availability of information

ISO 14971 Medical Device Risk Management

Process for risk management of medical devices, hardware and software

IEC 62304 Medical Device Software

Processes, activities and tasks for the efficient and safe life cycle of medical device software

IEC 62366-1 Medical Device Usability

Process to develop, and evaluate the usability of a medical device, ensuring it is efficient and safe

ISO 60601 Medical Electrical Equipment

Basic safety and essential performance of medical electrical equipment

Radio Equipment Directive (RED, 2014/53/EU)

Establishes a regulatory framework for placing radio equipment on the market

EN 301 489-01/17 Electromagnetic Compatibility (EMC)

Establishes the general technical requirements and test methods for EMC of radio equipment

EN 300 328 V2.2.2

Requirements and test methods for Wideband transmission systems operating in the 2.4 GHz band

EN-IEC 61000

Establishes testing and measurement techniques to ensure the immunity and safety of the device against Electrostatic Discharges (ESD), conducted and radiated emissions

EN 55011 CISPR 11

Establishes standards for methods of measurement for industrial, scientific and medical radio-frequency equipment

EN 303645

Cyber security requirements for Internet of Things

UL 2900 Software Cyber security

Cyber security requirements for network-connectable products, including medical devices and healthcare systems

General Data Protection Regulation 2016/679/EU (GDPR)

A regulation in EU law on data protection and privacy in the European Union and the European Economic Area. It also addresses the transfer of personal data outside the EU and EEA

Health Insurance Portability and Accountability Act (HIPAA)

A United States federal statute that stipulates how personally identifiable information, maintained by the healthcare and healthcare insurance industries, should be protected