SZUTEST

MEDICAL DEVICES

Reliable and Pioneering!

While being proud to be one of the most reliable and pioneering companies in certification and testing of Medical Devices, we are well aware of the importance of offering a single source solution to our clients for all requirements to launch their products, and we are striving to achieve this.

NOTIFIED BODY

A Member to Team NB, SZUTEST is the notified body no. 2195 appointed for Directive 93/42/EEC with a large scope and for that reason SZUTEST is fully authorized for CE certification of medical devices required for entry to the markets of Europe, Turkey and many other countries.

TESTING ACTIVITIES

With our increasing investments, we are continuously improving our testing capabilities for medical devices. Electrical safety tests of active medical devices based on Standard EN 60601-1+A1:2013 (version 3.1) and accredited biomechanical tests based on Standards ASTM F 382, ASTM F 384, ASTM F 543, ASTM F 1798, ASTM F 2193, ASTM F 1717, ASTM F 2077, ASTM F88 and ASTM D882 are carried out in our accredited laboratory.

ISO 13485

ISO 13485 Quality Management System is the absolute indicator of reliability for manufacturers, suppliers and distributors of medical devices, and it makes the holder a preferred company throughout the world. SZUTEST is accredited for ISO 13485 certification by TURKAK (Turkish Accreditation Agency) and IAS.