**CSA Approval** 

Medical Devices, Laser and Electrical Safety Branch Electrical and Electronics Laboratory



The Standards Institution of Israel is the only organization that maintains a CSA accreditation (Authorized Data Acceptance Program) and acts as a CSA Agency in Israel.

CSA recognizes tests performed by SII and accepts SII reports without actual presence of a CSA representative during testing and without sending samples of equipment to CSA.

This accreditation was granted following a thorough inspection of the proficiency of SII staff and its capabilities to fulfill the tasks at the level required by CSA as well as annual reassessments.

## Types of products for CSA certification:

- all kinds of medical devices and systems;
- information technology equipment;
- measuring, control and laboratory equipment

## Types of CSA Marks (different programs):

Program 1: International Certification (for the World): SII performs all testing, report preparation, technical support and communication with CSA throughout the whole project until receipt of CSA certification

Based on IEC60601-1(ed.3.1) series of standards and US and CA National Differences. Certificate of Compliance and CSA Descriptive Report (for factory inspections) are issued



## Program 2: Special Inspection (Canada only)

SII provides assistance with arranging CSA Special Inspection for customers

Applicable if there is no certification program for a particular type of product or if the certification program cannot be applied.

Markings:



Program 3: Field Certification (North America) SII provides assistance with arranging Field Evaluation for customers Controlled testing on site or at CSA test facilities

For a known quantity of products (batch type). All products must be tested in a batch.

Markings:



Program 4: National Certification (North America) SII provides assistance with arranging National Certification for customers Each product must be certified under its own Canadian or American applicable standard. Certificate of Compliance and CSA Descriptive Report (for factory inspections) will be issued.

For further details: Irina Antonov Head of Medical Devices, Laser and Electrical Safety Branch Electrical and Electronics Laboratory Telephone: +972-3-6467804, +972-52-3285109, E-mail: <u>antonovi@sii.org.il</u>