

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

SCC Soft Computer

(FIN F003201)

Main Site: 5400 Tech Data Drive,

Clearwater, Florida, 33760, United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design, development, manufacture, installation, and service of standalone or integrated software for the functions of blood donor, blood transfusion and laboratory and genetics information systems.

Certificate Number:

0088682-02

Initial Certification Date:

2019-03-24

Date of Certification Decision:

2023-03-22

Certification Effective Date:

2023-03-23

Certification Expiry Date:

2025-03-23





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Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc. 900 Chelmsford Street Lowell, MA, USA 01851



