

# CERTIFICATE OF 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:**

0088682-01

**Initial Certification Date:**

2019-03-24

**Date of Certification Decision:**

2022-03-18

**Certification Effective Date:**

2022-03-23

**Certification Expiry Date:**

2023-03-23



intertek

**Calin Moldovean**

President, Business Assurance

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