

## **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: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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

**Revision Level: 04** 

**Initial Certification Date:** 

2019-03-24

**Certification Effective Date:** 

2025-03-23

**Certification Expiry Date:** 

2028-03-23



MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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