

CERTIFICATEOF REGISTRATION

This is to certify that the management system of:

Clinical Computer Systems, Inc.

(FIN F000780)

Main Site: 2895 Greenspoint Parkway, Suite 500,

Hoffman Estates, Illinois, 60169-7262, 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)

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 support of software used to capture, display and archive perinatal data.

Certificate Number:

0085609-02

Initial Certification Date:

2018-12-28

Date of Certification Decision:

2022-01-05

Certification Effective Date:

2022-01-05

Certification Expiry Date:

2024-12-27



MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean

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