

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Chrono-log Corporation

(FIN F000776)

Main Site: 2 West Park Road
Havertown, PA 19083 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:

Design, Manufacture, Installation, Service and Distribution of Platelet Aggregometers, Reagents for Platelet Aggregation, Ristocetin Cofactor Assay Kits and Cuvettes.

Certificate Number:

0085301-01

Initial Certification Date:

2018-12-18

Date of Certification Decision:

2021-12-07

Certification Effective Date:

2021-12-17

Certification Expiry Date:

2024-12-17



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Calin Moldovean

President, Business Assurance

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