

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

ACRA-CUT, Inc.

(FIN F000719)

Main Site: 989 Main Street

Acton, Massachusetts 01720 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)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

*The design and manufacture of sterile cranial perforators, wire pass drills,
cranioblades, distraction screws and scalp clips. Service of reusable
drills/perforators.*

Certificate Number:

0085357-03

Initial Certification Date:

2018-12-19

Date of Certification Decision:

2024-12-04

Certification Effective Date:

2024-12-18

Certification Expiry Date:

2027-12-18



intertek

Calin Moldovean

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