

# 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, manufacture and servicing of cranial perforators, wire pass  
drills, cranioblades, distraction screws and scalp clips.*

**Certificate Number:**

0085357-02

**Initial Certification Date:**

2018-12-19

**Date of Certification Decision:**

2024-03-06

**Certification Effective Date:**

2024-03-06

**Certification Expiry Date:**

2024-12-18



intertek

**Calin Moldovean**

President, Business Assurance

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