EC Certificate

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC on Medical Devices, Annex V

Certificate Number
41313640-02

Initial Certification Date
September 1, 2009

Certificate Valid from
November 6, 2015

Certificate Expiry Date
June 5, 2020

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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Ackred. nr 1003
ISO/IEC 17021

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

ACRA-CUT, Inc.

989 Main Street, Acton, Massachusetts 01720, USA

Product Category:

- Cranial Perforators
- Cranioblades and Wire Pass Drills
- Distraction Screws
- Scalp Clips Systems

For further identification of the products covered, see the MDD product list/product schedule.

November 6, 2015
Signed date

Mats Premfors, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2015-09-30