EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

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

Main Site: 989 Main Street, Acton, Massachusetts 01720, USA

Product Category:

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

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

Certificate Number:
41313640-04

Initial Certification Date:
01 September 2009

Certificate Valid from:
06 June 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

04 June 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

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.

MDD – Product List

Products included in the Certificate No: 41313640-04
Issued to: **ACRA-CUT, Inc.**
989 Main Street
Acton,
Massachusetts 01720
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Cranial Perforators	200-141	IIa	No		*
	200-151	IIa	No		*
	200-152	IIa	No		*
	200-171	IIa	No		*
	200-331	IIa	Yes		*
	200-241	IIa	Yes		*
	200-243	IIa	Yes		*
	200-245	IIa	Yes		*
	200-251	IIa	Yes		*
	200-253	IIa	Yes		*
	200-255	IIa	Yes		*
	200-271	IIa	Yes		*
	200-275	IIa	Yes		*
	200-283	IIa	Yes		*
	200-500	IIa	Yes		*
	210-221	IIa	Yes		*
Wire Pass Drills & Cranioblades	800-330	IIa	Yes		*
	800-130	IIa	Yes		*
	800-140	IIa	Yes		*
Scalp Clip Systems	500-101	IIa	Yes		April 17th, 2015
	500-102	IIa	Yes		*
	500-103	IIa	Yes		*
	500-104	IIa	Yes		*
	500-105	IIa	Yes		*
	500-106	IIa	Yes		*
	500-107	IIa	Yes		*
	500-108	IIa	Yes		*
	500-109	IIa	Yes		*
	500-110	IIa	Yes		*
	500-111	IIa	Yes		*
	500-112	IIa			*

* Product added before June 5, 2010.

Intertek Semko AB
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Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Sign Date: 4 June 2020
Valid Date: 6 June 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41313640-04
Date: 4 June 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

ACRA-CUT, Inc.
Attn: Jeff Baker
989 Main Street
Acton,
Massachusetts 01720
USA

Purpose	Assessment to issue a new certificate due to five year extension extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 12 November 2019 in Acton, Massachusetts by John Pulley and Mesfin Kassa The technical file was reviewed 1 June 2020 by Vincenzo Tilotta at Intertek's office.
Scope of assessment	- Cranial Perforators, - Cranioblades and Wire Pass Drills, - Scalp Clips Systems, Class IIa.
Result	0 non conformities were noted during the audit.
Certificate Valid from	6 June 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD