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
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
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.

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

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ACRA-CUT Inc.
989 Main Street
Acton, Massachusetts 01720
United States

11 December 2023

Notified Body Confirmation Letter
Reference: *MDD Cert 41371240-03- CN00213-02*

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ACRA-CUT Inc.
989 Main Street
Acton, Massachusetts 01720
United States
SRN Number (if available): US-MF-000013622

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment

procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
Model 500-100	Clip Applier	Ir	Class I MDD
Model 500-135	Clip Remover	Ir	Class I MDD
Model 500-103	Scalp Clips	IIa	41313640-04
Model 500-104	Scalp Clips	IIa	41313640-04
Model 500-105	Scalp Clips	IIa	41313640-04
Model 500-106	Scalp Clips	IIa	41313640-04
Model 500-108	Scalp Clips	IIa	41313640-04
Model 500-109	Scalp Clips	IIa	41313640-04
Model 500-110	Scalp Clips	IIa	41313640-04
Model 500-111	Scalp Clips	IIa	41313640-04
Model 500-112	Scalp Clips	IIa	41313640-04
Model 200-331	Cranial Perforator	IIa	41313640-04
Model 200-241	Cranial Perforator	IIa	41313640-04
Model 200-243	Cranial Perforator	IIa	41313640-04
Model 200-245	Cranial Perforator	IIa	41313640-04
Model 200-251	Cranial Perforator	IIa	41313640-04
Model 200-253	Cranial Perforator	IIa	41313640-04
Model 200-255	Cranial Perforator	IIa	41313640-04
Model 200-271	Cranial Perforator	IIa	41313640-04
Model 200-275	Cranial Perforator	IIa	41313640-04
Model 200-283	Cranial Perforator	IIa	41313640-04
Model 200-500	Cranial Perforator	IIa	41313640-04
Model 210-221	Cranial Perforator	IIa	41313640-04

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action