Manufacturer Evidence

Status : Approved

Certificate change history

Dear [redacted]

I have just spoken with the Australian Sponsor [redacted] who assures me that Eska Implants as indicated on the certification supplied is a separate company from Eska Med. It should have a separate entry on the ARTG.

Many thanks for your help- if you have any further queries please feel free to contact me on either of the numbers below.

[redacted]
version 2 - 3 new codes added - covered by EC certificate. [redacted]
Variation 3 - addition GMDNS code Unclassified [38442]. [redacted]
Variation 4 - addition code [44054]. [redacted]
Variation 5:Updated EC Certificate supplied. [redacted]

Date received :	20/11/2006
Certificate printed :	No

Variation to Evidence ID: DV-20050329-MC-001787-2

Notification details

Evidence identifier:	DV-20050329-MC-001787-2
Submission identifier:	DV-2006-4543
Version number:	5
Sponsor's own reference:	hp/eska implants/various 01

Sponsor details

Agent name:	SPECTRUM TECHNOLOGY PTY LTD
Sponsor name:	Eska Australia
Contact details:	[redacted]

Certification details

Manufacturer name:	Eska Implants GmbH and Co (Germany)[45325]
Manufacturer address as on certification:	GrapengieBerstraBe 34 Lubeck D-23556 Germany S [147473]

Type of product:
This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	02
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	Dekra Certification GmbH [0124]
Certificate number:	50088-16-02
Certificate issue date: (dd/mm/yyyy)	30/11/2001

Certificate expiry date: (dd/mm/yyyy)	29/11/2011
Certificate re-issue date: (dd/mm/yyyy)	30/11/2006

Restrictions on scope:

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents

- Updated EC Certificate - ESKA QA 1106 01.jpg
- Updated EC Certificate - ESKA QA 1106 02.jpg
- Declaration of Conformity - Easka 03.jpg
- Declaration of Conformity - Easka 04.jpg
- Add supporting documentation - Easka 06.jpg
- Declaration of Conformity - Easka 01.jpg
- Declaration of Conformity - Eska 01.jpg
- Declaration of Conformity - Easka 05.jpg

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

CN=[redacted]OU=TGA/O=Health