CERTIFICATE

for the

Quality Assurance System

DEKRA Certification

As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

ESKA Implants GmbH & Co. KG

Grapengießerstraße 34 • D-23556 Lübeck

The approval is based on the result of the certification audit with report number 50088-Z3-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	03.12.1996	Date of the last recertification:	30.11.2006
This certificate is valid until:	29.11.2011	Certificate-registration No.:	50088-16-02

English version

[redacted]

DEKRA Certification GmbH
Stuttgart, 17.11.2006

Akkreditiert durch Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the Certificate 50088-16-02 dated 17.11.2006

English version

Revision status: 0 Date: 30.11.2006 Page 1 of 1

Devices/device categories included in the certificate

Class II b:

- Hip endoprosthesis systems
- Femur neck prosthesis
- Knee endoprosthesis systems
- Shoulder Endoprosthesis systems
- Modular system for hip, knee, shoulder, and ellbow treatment
- Ankle joint endoprosthesis systems
- Spinal endoprosthesis systems
- Finger endoprosthesis system
- Modular Hip, ESKA-BIONIK®-System
- Integrated Prosthesis System, Endo-Exo-Prosthesis
- Great Toe Main Joint
- Cera-Metal Coating for Hip Endoprosthesis System and Hip Surface Replacement System BS
- Dental implants ESKA-DENT

DEKRA

INDUSTRIAL

Anlage zum Zertifikat 50088-16-01 vom 30.11.2001

Revisionsstand: 2 Datum: 29.03.2005 Seite 1 von 1

In die Genehmigung eingeschlossene Medizinprodukte / Produktkategorien

Klasse II b:

- Hüft-Endoprothesen-Systeme
- Schenkelhalsprothesen
- Knie-Endoprothesen-Systeme
- Schulter-Endoprothesen-Systeme
- Modularsystem zur Versorgung von Hüfte, Knie, Schulter und Ellenbogen
- Sprunggelenk-Endoprothesen-Systeme
- Wirbelsäulen-Endoprothesen-Systeme
- Finger-Endoprothesensystem
- Modulare Hüfte, Bionik-System
- Integrales Prothesen System, Endo-Exo Prothese
- Großzehengrundgelenk

DEKRA Intertek Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

DEKRA

---- Original Message ----
From: Sicherheitsbeauftragter ESKA Implants GmbH & Co.
To: Paul West
Sent: Tuesday, April 05, 2005 4:21 PM
Subject: Re: Literature Update

Hi Paul Jimmy

Unfortunately the attached certifcate is only available in German.
The last three positions mean:

- Modulare Hüfte Bioomik-System => Modular Hip Bionic System (including "Surf"-Surface)
- Integales Prothesen System Endo-Exo-Prothese => Integrated Prostheses System Endo-Exo-Prostheses
- Großzehengrundgelenk => Great Toe Basic Joint

Best Regards

Geord

6/7/05

Adtronic device covered by existing evidence previously submitted

[redacted]

DEKRA-ITS
CERTIFICATION SERVICES

Annex to the Certificate 50088-16-01 dated 30.11.2001

English version

Revision status: 0 Date: 30.11.2001 Page 1 of 1

Devices/device categories included in the certificate

Class II b products:

- Hip endoprosthesis systems
- Femur neck prosthesis
- Knee endoprosthesis systems
- Shoulder Endoprosthesis systems
- Modular system for hip, knee, shoulder, and ellbow treatment
- Ankle joint endoprosthesis systems
- Spinal endoprosthesis systems
- Finger endoprosthesis system

DEKRA-ITS Certification Services GmbH • D-70565 Stuttgart, Handwerkstraße 15 •
DEKRA-ITS CERTIFICATION SERVICES

CERTIFICATE

for the

Quality Assurance System

As a notified body of the European Union (Reg. No. 0124), DEKRA-ITS Certification Services GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

ESKA Implants GmbH & Co.

Location:

Grapengießerstraße 34 • D - 23556 Lübeck

Approval is based on the result of the certification audit with report number 50088-Z2-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	03.12.1996	Date of the last recertification:	30.11.2001
This certificate is valid until:	29.11.2006	Certificate-registration No.:	50088-16-01

[redacted]

DEKRA-ITS Certification Services GmbH
Stuttgart, 15.03.2002

Modular System - adaptor (MMC
unclassified device - See rule 6