

CERTIFICATE

DOCUMENT 29

for the Quality Assurance System



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.

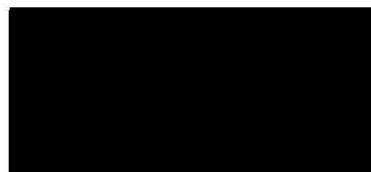


Date of the first
certification: 03.12.1996

This certificate is
valid until: 29.11.2011

Date of the last
recertification: 30.11.2006

Certificate-
registration No.: 50088-16-02
English version



DEKRA Certification GmbH
Stuttgart, 17.11.2006



Akkreditiert durch
Zentralfür Gesundheitschutz
für Gesundheitschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-992.94.18

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 elbow 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



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 / ProduktkategorienKlasse 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



—— 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

Unfortunately the attached certificate is only available in German.

The last three positions mean:

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

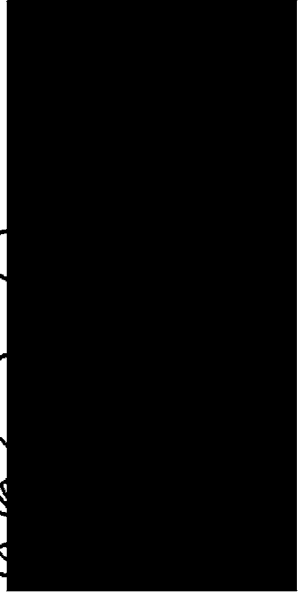
Best Regards

Good

6/7/05

Additional device covered by
existing evidence previously
submitted

Heath



Annex to the Certificate 50088-16-01 dated 30.11.2001

English version

Revision status: 0

Date: 30.11.2001

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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 elbow treatment
- Ankle joint endoprosthesis systems
- Spinal endoprosthesis systems
- Finger endoprosthesis system



CERTIFICATE

for the

Quality Assurance System



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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.



Date of the first
certification: 03.12.1996

This certificate is
valid until: 29.11.2006

Date of the last
recertification: 30.11.2001

Certificate-
registration No.: 50088-16-01

DEKRA-ITS Certification Services GmbH
Stuttgart, 15.03.2002

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

Modular System - adaptor (mmc)
unclassified device - see rule 1a