

ZEISS

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Vaše Č.J.:

Vaše zpráva:

Naše Č.J.:

Datum: 02.04.2007

Oddělení: MED

Vyřizuje: Jana Filipová

Ujištění o vydání Prohlášení o shodě

firma Carl Zeiss spol. s r. o. tímto ujišťuje, že výrobce chirurgických přístrojů, firma Carl Zeiss Meditec AG, Jena, Německo, vydala Prohlášení o shodě na přístroj

Stratus OCT

Třída ZP: IIa

Prohlášení o shodě je k dispozici v sídle společnosti ČR: Carl Zeiss spol. s r. o., Radlická 14/3201, Praha 5.

S pozdravem

Jana Filipová
odd. lékařská přístrojová technika

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Zapsáno v OR u Měst. soudu v Praze,

ddíl C, vložka 19868

Česká spořitelna, a.s.

Bankovní spojení: 192 428 7309/0800

HVB BANK CZECH REPUBLIC, a.s.

Bankovní spojení: 328 536 1005/2700

Jednatel:

Dipl.- Ing. Manfred Oemler

Prokurista:

Vlastislav Troják

MUDr. Roman Vanžura

Ing. Jiří Vilknér



CARL ZEISS MEDITEC

P/N: 4-21-F-01 REV: Q
TITLE: Declaration of Conformity Form

DECLARATION OF CONFORMITY

Manufacturer: CARL ZEISS MEDITEC INC.

Address: 5160 Hacienda Drive
Dublin, CA 94568
USA

Product Name/Designation: STRATUSoc
Model(s): 3000

We declare the above mentioned product(s) meet the provisions of the EC Directive 93/42/EEC which applies to them, as stated in Annex II of this directive for a Class IIa device

The product is labeled with the **CE** marking
DQS GmbH Notified Body Number: 0297

EU REPRESENTATIVE
Carl Zeiss Meditec AG
Goeshwitzer Strasse 51-52
Jena, D-07745
Germany

This declaration is based on:

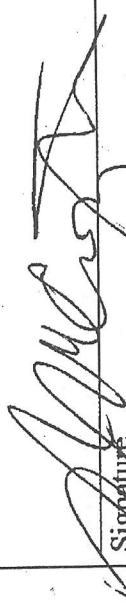
Certificate of Quality System: DIN EN ISO 9001:1994 & DIN EN ISO 13485:2001


Certification Registration No.: 250712 Q1 & 250712 MP21

Issued By: DQS GmbH German Registrar For Management Systems

Place: August-Schanz-StraBe 21
Frankfurt a.M., 60433
Germany

Date of Expiry: 2003-12-14 & 2007-03-19


Signature
VP, Regulatory/Clinical Affairs & Quality Assurance
Date 11/27/02


Signature
VP, Research and Development
Date 11/27/02



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