

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60098144 0001

Report No.: 21220125 001

Manufacturer: Dornier MedTech GmbH
Argelsrieder Feld 7
82234 Weßling
Deutschland

Products: see attachment for products and sites included

Expiry Date: 2019-12-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2014-12-30

Date: 2014-12-30

Notified Body

Zweitschrift/Copy 2015-01-27

Dipl.-Ing. D. Meier



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60098144 0001
Report No.: 21220125 001

Manufacturer: Dornier MedTech GmbH
Argelsrieder Feld 7
82234 Weßling
Deutschland

Products included:

- extra-corporal Shock Wave Lithotripter (ESWL)
- Devices for extra-corporal Shock Wave Therapy
- Laser Surgical Equipment
- sterile Laser Waveguides
- non-sterile Laser Applicators
- Radiographic Fluoroscopic Tables
- Patient Stretchers
- Peristaltic Pumps
- Image survey for Shock Wave Therapy

Date: 2015-01-13

Notified Body

Zweitschrift/Copy 2015-01-21

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60098144 0001
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Manufacturer: Dornier MedTech GmbH
Argelsrieder Feld 7
82234 Weßling
Deutschland

Sites included:

- Dornier MedTech Laser GmbH
Argelsrieder Feld 7
82234 Wessling, Germany

Activities associated with the Design, Development
and Manufacturing of Laser Surgical Equipment, sterile Laser
Waveguides, non-sterile Laser Applicators and Peristaltic
Pumps

- Dornier MedTech Systems GmbH
Argelsrieder Feld 7
82234 Wessling, Germany

Activities associated with the Design, Development and
Manufacturing of Shock Wave Application Equipment, Radio-
graphic Fluoroscopic Tables, Patient Stretchers and
Image Survey for Shock Wave Therapy

Notified Body

Zwertschrift/Copy 2015-01-27

Date: 2015-01-13

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60098144 0001
Report No.: 21220125 001

Manufacturer: Dornier MedTech GmbH
Argelsrieder Feld 7
82234 Weßling
Deutschland

Sites included:

- | | |
|---|--|
| - Dornier MedTech Italia
Sede Legale
Via A. Cavaglieri, 26
00173 Rome, Italy | - Dornier MedTech Espana S.L.
Pedro y Pons, 9-11
Edificio Master's
08034 Barcelona, Spain |
| - Dornier MedTech Europe GmbH
Argelsrieder Feld 7
82234 Wessling, Germany | |

Activities associated with the Installation, Service and Distribution of Shock Wave Application Equipment, Laser Surgical Equipment, sterile Laser Waveguides, non-sterile Laser Applicators, Radiographic Fluoroscopic Tables, Patient Stretchers and Image Survey for Shock Wave Therapy

Notified Body



Zweitschrift/Copy 2015-01-27

Date: 2015-01-13

Dipl.-Ing. D. Meier

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60098144 0001
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Manufacturer: Dornier MedTech GmbH
Argelsrieder Feld 7
82234 Weßling
Deutschland

Sites included:

- Dornier MedTech Asia Pte. Ltd.
51 Corporation Road
Singapore 649806, Singapore
- Dornier MedTech Japan Co. Ltd.
Meguro Estate Building
3-8-5 Kami Ohsaki, Shinagawa-ku
Tokio 141, Japan

Activities associated with the Installation, Service and Distribution of Shock Wave Application Equipment, Laser Surgical Equipment, sterile Laser Waveguides, non-sterile Laser Applicators, Radiographic Fluoroscopic Tables, Patient Stretchers and Image Survey for Shock Wave Therapy

Notified Body



Date: 2015-01-13

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Dipl.-Ing. D. Meier