

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

Registration No.: HD 60115150 0001

Report No.: 21256460 001

Manufacturer: STORZ MEDICAL AG
Lohstampfstr. 8
8274 Tägerwilen
Schweiz

Products:

- Equipment for the extracorporeal induced shock wave and pressure pulse therapy for stationary and mobile use
- X-ray application devices (without radiation components)

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60103173 0001

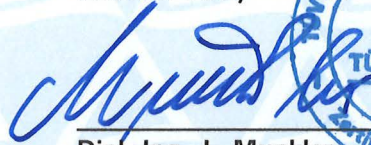
Expiry Date: 2021-11-18

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: 2017-08-02

Date: 2017-08-02

Notified Body


Dipl.-Ing. I. Munkler

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

Doc. 1/3, Rev. 2

**Attachment to
Certificate**

Registration No.: HD 60115150 0001
Report No.: 21256460 011

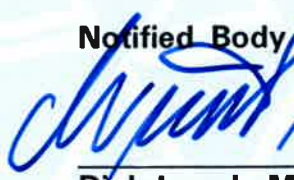
Manufacturer: STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

Equipment for the extracorporeal induced shock wave therapy
for stationary and mobile use:

- MODULITH SLK
with options
 - LITHOTRACK
 - US-SET
- MODULITH SLX-F2
with options
 - C-ARM C-MX
 - US-SET
 - StörM-Touch
 - MONITORARM

Date: 2019-06-03

Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 2

**Attachment to
Certificate**

Registration No.: HD 60115150 0001
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Manufacturer: **STORZ MEDICAL AG**
Lohstampfstr. 8
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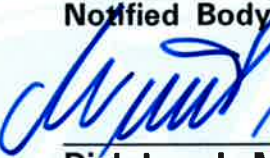
X-ray application devices (without radiation components):
- C-MX

Equipment for the extracorporeal pneumatically operated
ballistic pressure wave therapy:

- MASTERPULS MP100
- MASTERPULS MP200
- MASTERPULS MP50
- MASTERPULS ONE
- D-ACTOR 100
- D-ACTOR 200
- D-ACTOR 50
- D-ACTOR ONE
- CHATTANOOGA MOBILE RPW - 2805
- CHATTANOOGA MOBILE 2 RPW - 2905
- CHATTANOOGA INTELECT RPW Lite

Date: 2019-06-03

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Registration No.: HD 60115150 0001
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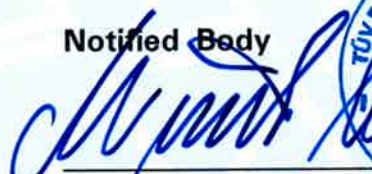
Manufacturer: **STORZ MEDICAL AG**
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8274 Tägerwilen
Schweiz

Equipment for the extracorporeal induced shock and pressure
wave therapy for stationary and mobile use:

- DUOLITH SD1 T-Top [001x]
- DUOLITH SD1 T-Top [010x]
- DUOLITH SD1 Tower
- CELLACTOR SC1 T-Top
- CELLACTOR SC1 Tower
- CELLIMPACT
- CHATTANOOGA INTELECT F-SW - 21095
- W-MEDICAL SHOCKWAVE F1
- NEUROLITH

Date: 2019-06-03

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