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
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

Digitally signed by Cucerenco Olesea
Date: 2019.10.22 15:29:03 EEST
Reason: MoldSign Signature
Location: Moldova

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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
  - StorM-Touch
  - MONITORARM

Notified Body

TÜV Rheinland LGA Products GmbH – Zertifizierungsstelle – TÜVRheinland®

Date: 2019-06-03

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 2/3, Rev. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60115150 0001
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Manufacturer: STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
Schweiz

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
- CHATANOOGA INTELECT RPW Lite

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date: 2019-06-03

TÜVRheinland®

Doc. 3/3, Rev. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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 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

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle