

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

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

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Notified Body

Dipl.-Ing. I. Munkler

VRheinland

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.