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 15:29:09 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.

Notified Body

Effective Date: 2017-08-02

Date: 2017-08-02

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.