

EC Certificate



Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1499629-1

Manufacturer: LASOTRONIX Sp. z o.o.
Elektroniczna 2A
05-500 Piaseczno
Poland

Products: - Medical diode lasers

Replaces EC Certificate number HD 1499629-1 dated 2020-07-16

A large, light blue watermark of the TÜVRheinland logo is centered on the page. It consists of a stylized triangle with a registered trademark symbol (R) and the text 'TÜVRheinland' below it.

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.

Report No.: 84953464-20

Effective date: 2021-05-25

Expiry date: 2024-05-26

Issue date: 2021-05-25

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

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SMART M laser, models:

- SMART M ST1
- SMART M ST2
- SMART M ST3
- SMART M DR1
- SMART M DR2
- SMART M DR3
- SMART M SG1
- SMART M SG2
- SMART M SG3
- SMART M SG4
- SMART M SG5
- SMART M GN1
- SMART M GN2
- SMART M GN3
- SMART M PH1
- SMART M PH2
- SMART M PH3
- SMART M PH4
- SMART M LG1
- SMART M LG2
- SMART M NS1
- SMART M VT1

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