



Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Warsaw, 23-09-2024

CERTIFICATE OF FREE SALE No. 557/2024

In reference to application for a free sale certificate made by the

Lasotronix Sp. z o.o.
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device

Type

Medical diode laser

According to attachment

manufactured by:

Lasotronix Sp. z o.o.
Elektroniczna 2A, 05-500 Piaseczno, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1) 'Regulation 2017/745', in accordance with the rules laid down in that Regulation. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski



Certificate of Free Sale is issued pursuant to Article 67(1) of the Act of 20 May 2010 on Medical Devices in connection with Article 138(6) of the Act of 7 April 2022 on Medical Devices (Journal of Laws of 2022, item 974, as amended) and Article 120(3) of Regulation 2017/745.

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GDPR - Information on the processing of personal data can be found on the website of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products



Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Attachment to the Free Sale Certificate number 557/2024 from: 23-09-2024

TRADE NAME OF DEVICE: Medical diode laser

TYPE:

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

This attachment is valid only with the original certificate.