

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60126575 0001

Report No.: 26300257 005

Manufacturer: "Elektronika i Elektromedycyna"
M. Lewandowski Spolka Jawna
ul. Zacisza 2
05-402 Otwock
Poland

Products: (see attachments for products and sites included)
Replaces EC Certificate, Registration No.: HD 60098841 0001

Expiry Date: 2023-01-24

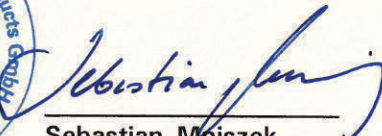
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, 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: 2018-01-25

Date: 2018-01-25



Notified Body


Sebastian Miszek

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 1

**Attachment to
Certificate**

Registration No.: HD 60126575 0001
Report No.: 26300257 007

Manufacturer: "Elektronika i Elektromedycyna"
M. Lewandowski Spolka Jawna
ul. Zacisza 2
05-402 Otwock
Poland

Products included:

- Electrotherapy devices
- Magnetic field therapy devices
- Laser therapy devices
- Ultrasound therapy devices
- Carbon dioxide therapy devices

Date: 2019-09-06

Notified Body

M. Pyclik



Jaroslav Pyclik

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60126575 0001
Report No.: 26300257 005

Manufacturer: "Elektronika i Elektromedycyna"
M. Lewandowski Spolka Jawna
ul. Zacisza 2
05-402 Otwock
Poland

Sites included:

"Elektronika i Elektromedycyna"
M. Lewandowski Spolka Jawna
ul. Graniczna 81a
05-420 Jozefow
Poland

Activity: Design/development and manufacture

Date: 2018-01-25



Notified Body


Sebastian Mniszek