

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1023653-1

Organization: „Elektronika i Elektromedycyna”
M. Lewandowski Spółka Jawna
ul. Zaciszna 2
05-402 Otwock
Poland

Scope: Design and development, manufacture, distribution and servicing of electrotherapy devices, magnetic field therapy devices, laser therapy devices, ultrasound therapy devices and carbon dioxide therapy devices as well as related accessories

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84950696-20

Effective date: 2021-02-25

Expiry date: 2023-12-17

Issue date: 2021-02-25

Maciej Ściera



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TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	„Elektronika i Elektromedycyna” M. Lewandowski Spółka Jawna ul. Zaciszna 2 05-402 Otwock Poland	Distribution of active therapeutic devices
/02	„Elektronika i Elektromedycyna” M. Lewandowski Spółka Jawna ul. Graniczna 81a 05-420 Józefów Poland	Design and development, manufacture and servicing of active therapeutic devices

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