

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 1962094-1



Manufacturer: **Astar Spółka z ograniczoną odpowiedzialnością**
ul. Świt 33
43-382 Bielsko-Biała
Poland

EUDAMED Single
Registration No.: PL-MF-000010564

Products: Products of class IIa:
Z120601 - ELECTROTHERAPY EQUIPMENT
Z120602 - PHYSIOTHERAPY EQUIPMENT
Z120610 - ULTRASOUND THERAPY EQUIPMENT

Product of class IIb:
Z120602 - PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS
PHYSIOTHERAPY EQUIPMENT
Z120615 - PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS
THERAPEUTIC LASERS
Z120690 - PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS
VARIOUS PHYSIOTHERAPY AND REHABILITATION INSTRUMENTS

Authorised
representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-08-02

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 84962664-20
Effective date: 2023-08-02
Expiry date: 2028-08-01
Issue date: 2023-08-02



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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

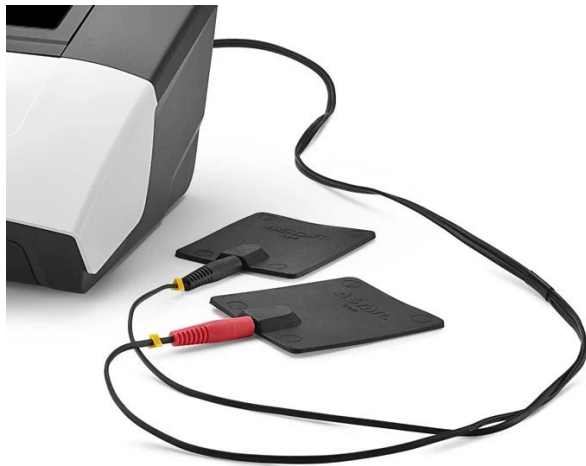


Type of electrodes for Astarelectrotherapy devices:

A-AE-AST-EL6060RV2- Silicon-carbon electrode 6x6 cm

A-AE-AST-EL7590RV2- Silicon-carbon electrode 7,5x9 cm

H-AE-THX-ELSIL6x12 - Silicon-carbon electrode 6x12 cm





Regeneration kit for shockwave therapy unit (Impactis M/ Impactis M+)

Code number: A-AF-AST-IMMREG



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1962094-1

Certificate Holder: Astar Spółka z ograniczoną odpowiedzialnością
ul. Świt 33
43-382 Bielsko-Biała
Poland

Scope: Design and development, production, distribution, installation and service of active medical devices for electrotherapy, laser therapy, IR therapy, ultrasound therapy, ultrasound therapy combined with electrotherapy, magnetic field therapy, vacuum therapy, shock wave physical therapy and radio frequency current physical therapy

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.: 84970271-20

Effective date: 2024-01-12

Expiry date: 2025-12-16

Issue date: 2024-01-12

Replaces certificate SX 1962094-1 issued 2022-12-16



Jarosław Pyclik
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Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1962094-1
Certificate Holder: Astar spółka z ograniczoną odpowiedzialnością
ul. Świt 33
43-382 Bielsko-Biała
Poland

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	Astar Spółka z ograniczoną odpowiedzialnością ul. Świt 33 43-382 Bielsko-Biała Poland	Production, distribution, installation and service of active medical devices for electrotherapy, laser therapy, IR therapy, ultrasound therapy, ultrasound therapy combined with electrotherapy, magnetic field therapy, vacuum therapy, shock wave physical therapy and radio frequency current physical therapy.
/02	Astar Spółka z ograniczoną odpowiedzialnością ul. Bielska 84 43-384 Jaworze Poland	Design and development of active medical devices for electrotherapy, laser therapy, IR therapy, ultrasound therapy, ultrasound therapy combined with electrotherapy, magnetic field therapy, vacuum therapy, shock wave physical therapy and radio frequency current physical therapy.

Report No.: 84970271-20
Effective date: 2024-01-12
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Model of viscose covers for electrotherapy electrodes:

A-AE-AST-PW8X8 - Viscose electrode cover 8x8 cm

A-AE-AST-PW10X10 - Viscose electrode cover 10x10 cm

A-AE-AST-PW8X14 - Viscose electrode cover 8x14 cm

