EU Certificate

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

TÜVRheinland®

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

Digitally signed by Ceaicovschi Tudor
Date: 2024.07.11 14:28:39 EEST
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Location: Moldova

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-091

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.