

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 PL-MF-000010564
Registration No.:

Products:

Products of class IIa:

Z120601 - ELECTROTHERAPY EQUIPMENT

Z120602 - PHYSIOTHERAPY EQUIPMENT

Z120606 - MAGNETOTHERAPY EQUIPMENT

Z120610 - ULTRASOUND THERAPY EQUIPMENT

Z120611 - VACUUM THERAPY EQUIPMENT

Z120614 - INFRARED ULTRAVIOLET RAY LAMPS

Product of class IIb:

Z120602 - PHYSIOTHERAPY AND REHABILITATION
INSTRUMENTS

PHYSIOTHERAPY EQUIPMENT

Z120615 - PHYSIOTHERAPY AND REHABILITATION
INSTRUMENTS

THERAPEUTIC LASERS

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.: 84970271-180

Effective date: 2024-06-14

Expiry date: 2028-08-01

Issue date: 2024-06-14

Jarosław Pyclik

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

This certificate can be validated on <https://www.certipedia.com>

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Z120690 - PHYSIOTHERAPY AND REHABILITATION
INSTRUMENTS
VARIOUS PHYSIOTHERAPY
AND REHABILITATION INSTRUMENTS
Z12139001 - ORTHOPEDIC INSTRUMENTS
SHOCK WAVE THERAPY EQUIPMENT

Authorized representative(s): Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-08-02
1	Scope extension	2024-06-14

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