EC Certificate

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

Registration No.: HD 60146581 0001

Report No.: 26300490 002

Manufacturer:
Astar Spółka z Ograniczoną
Odpowiedzialnością
ul. Świt 33
43-382 Bielsko-Biała
Polska

Products: see attachment for products and site included

Expiry Date: 2024-05-26

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: 2020-02-12

Date: 2020-02-12

Notified Body

Maciej Sciera

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146581 0001
Report No.: 26300490 002

Manufacturer:
Astar Spółka z Ograniczoną Odpowiedzialnością
ul. Świt 33
43-382 Bielsko-Biała
Polska

Products included:
- Electrotherapy devices
- Laser therapy devices
- IR therapy devices
- Magnetic field therapy devices
- Ultrasound therapy devices
- Ultrasound therapy combined with electrotherapy devices
- Vacuum therapy devices
- Shock wave physical therapy devices

Additional site included:

Astar Sp. z o.o.
ul. Pod Mlynska Kepa 748
43-384 Jaworze, Poland

Activity: Manufacture

Notified Body

Ściera Maciej

Maciej Sciera

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-02-12