Anexa 2 Dispozitiv pentru terapie cu ultrasunet, 1MHz si 3 MHz, Model: Sonaris S, Astar Polonia

Parametri solicitati	Parametri oferiti
Un echipament de terapie cu ultrasunete microcontrolerat, cu frecvențe de 1 MHz și 3 MHz; Pentru a fi utilizate în fizioterapie și estetică; Să ne permite să alegem zona de radiații efective (ERA) de 7 cm² sau 3 cm²; Modul de emisie cu ultrasunete poate fi reglat în mod continuu sau pulsatoriu, Modul pulsatoric cu frecvență de repetiție a impulsului de 100 Hz sau 48 Hz sau 16 Hz și cu raport puls de 1/2 (50%) și 1/5 (20%); Posibilitatea de alegerea a programelor de tratament pre-programate.	Un echipament de terapie cu ultrasunete microcontrolerat, cu frecvențe de 1 MHz și 3,5 MHz; Poate fi utilizate în fizioterapie și estetică; Permite să alegem zona de radiații efective (ERA) de 1 cm² si 4 cm²; Modul de emisie cu ultrasunete poate fi reglat în mod continuu sau pulsatoriu, Modul pulsatoric cu frecvență de repetiție a impulsului de 16 Hz , 48 Hz , 100 Hz și cu raport puls de 10%, 25%, 50%, 75%; Programe prestabilite de catre producator: 52 Posibilitatea de alegerea a programelor de tratament pre-programate. Accesorii: Sonda ultrsunet GS-1 -1 buc Sonda ultrsunet GS-4 -1 buc

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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.

TÜVRheinland®

Doc. 1/1, Rev. 0

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following scope:

see attachment for scope and site included

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-02-12
Certificate Registration No.:	SX 60146582 0001
An audit was performed. Report No.:	26300490 002
This Certificate is valid until:	2022-12-16

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-02-12

Maciej Sciera

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60146582 0001
Report No.: 26300490 002

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

Scope:

Design and development, manufacture, distribution, installation and servicing of active medical devices for electrotherapy, laser therapy, IR therapy, ultrasound therapy, magnetic field therapy, vacuum therapy and shock wave physical therapy

Additional site included:

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

Activity: Manufacture

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2020-02-12

Maciej Sciera

Sonaris S

Ultrasound therapy

Features

product code	A-US-AST-SMSWH
large, easy-to-read display with graphic mode support	✓
independent treatment channels	1
manual mode	✓
disease entities selected by name	✓
preset treatment programs database	✓
user-defined programs database	✓
possibility of program names edition	✓

Ultrasound therapy

waterproof ultrasound heads	✓
continuous / pulse emission	✓
ultrasound head contact control (effective treatment time measured)	✓
head sensitivity calibration according to the needs	✓

Preset treatment programs

built-in treatment programs for ultrasound therapy	52
user configurable programs	10

Ultrasound therapy technical parameters

operating frequency	1 & 3,5 MHz
effective radiation area	1 cm2, 4 cm2
maximum ultrasound wave intensity	2,5 W/cm²
frequency in pulse mode	16 Hz, 48 Hz, 100 Hz
duty factor in pulse mode	10%, 25%, 50%, 75%
treatment timer	1 - 30 minut

General technical parameters

dimensions	30 x 23 x 11cm
device weight	2,5 kg
power supply, power consumption	230 V, 50/60 Hz, 75 W, 90 VA