Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către: Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale
nr. 41 din 18.09.2023

Solicitantul „GBG-MLD" SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2, tel./fax: 022 54 73 73, e-mail office@gbg.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a producatorului **ASTAR,** cu următoarele poziții:

Product Name	SRN (Single Registration Number)	Basic UDI-DI
Multifunctional unit PhysioGo.Lite Combo	PL-MF-000010564	590364150PLCKB

Se anexează următoarele acte:
Notificarea pentru inregistrarea dispozitivelor medicale
Declaratia pe proprie raspundere
Declaratii de conformitate.
Scrisoarea de Autorizare
Certificat CE

Data _____ Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Digitally signed by Ceaicovschi Tudor
Date: 2023.11.10 15:15:23 EET
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE
Către: Agenția Medicamentului și Dispozitive Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: „GBG-MLD" SRL, cu sediul în mun. Chișinău, str. Albisoara 64/2,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru înregistrarea dispozitivelor producătorului **ASTAR** pentru întroducerea și punerea la dispoziție pe piață a următoarelor produse:

Product Name	SRN (Single Registration Number)	Basic UDI-DI
Multifunctional unit PhysioGo.Lite Combo	PL-MF-000010564	590364150PLCKB

Sunt autentice și corespund realității.`

Cristina GUȚU, Șef Secție „GBG-MLD" SRL

Semnătura _____

Data _____

DECLARATION OF CONFORMITY UE no. MDR-EU-PLC-EN

1.	MANUFACTURER NAME	**ASTAR SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ**
	SRN (SINGLE REGISTRATION NUMBER)	**PL-MF-000010564**
	ADDRESS	ul. Świt 33 43-382 Bielsko–Biała, Poland
2.	**The EU declaration of conformity is issued under the sole responsibility of the manufacturer.**	
3.	Basic UDI-DI	**590364150PLCKB**
4.	PRODUCT NAME	Multifunctional unit PhysioGo.Lite Combo
	CATALOGUE NUMBER	A-UC-AST-PLC
5.	INTENDED PURPOSE	Multifunctional unit PhysioGo.Lite Combo is an active, non-invasive therapeutic device, intended for carrying out treatment procedures using bipolar (bidirectional) and unipolar (unidirectional) low frequency currents, bipolar (bidirectional) and unipolar (unidirectional) medium frequency currents, standard ultrasound therapy, low-intensity pulsed ultrasound (LIPUS) therapy and phonophoresis or combination method of current and ultrasounds therapy. Treatments are performed by direct contact method with non-injured skin. Parts of the body intended for treatments with PhysioGo.Lite Combo are back, upper limbs (shoulder, arm, forearm, hand), lower limbs (hip, thigh, shank, foot), neck and face for interaction with body tissues such as muscle, skeletal, nervous system and/or skin.
6.	CLASSIFICATION	RISK CLASS IIa
		RULE 9
7.	We declare that the device that is covered by the present declaration is in conformity with the Regulation (EU) 2017/745 of the European Parliament and of the Council, Directive 2011/65/EU of the European Parliament and of the Council and Commission Delegated Directive 2015/863/EU.	
8.	COMMON SPECIFICATIONS	Not applied
9.	NAME OF THE NOTIFIED BODY	TÜV Rheinland LGA Products GmbH
	IDENTIFICATION NUMBER OF THE NOTIFIED BODY	0197
	CONFORMITY ASSESSMENT PROCEDURE	Article 52, p. 6 of Regulation (EU) 2017/745 of the European Parliament and of the Council (Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex)
	IDENTIFICATION OF THE CERTIFICATES	QMS: SX 1962094-1
		EC: HZ 1962094-1
10.	ADDITIONAL INFORMATION	Not applied
11.	PLACE AND DATE OF ISSUE OF THE DECLARATION	Bielsko-Biała, 02.08.2023
	NAME OF THE PERSON WHO SIGNED THE DECLARATION	Robert Dziendziel
	FUNCTION	MEMBER OF THE BOARD
	ON BEHALF	CHAIRMAN OF THE BOARD
	SIGNATURE	

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.

ASTAR.

Bielsko-Biała, 29.08.2023

To: Agentia Medicamentului si Dispozitivelor Medicale

We, Astar Spółka Z Ograniczoną Odpowiedzialnością, (manufacturer), having a registrated office at: 33 Świt Street, 43-382 Bielsko-Biała, Poland, TIN: PL5472113926,

Assign:

"GBG-MLD" SRL, having a registrated office at Str. Albisoara 64/2, Chisinau MD -2005, Moldova, as **authorized representative** in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Bielsko-Biała Date:29.08.2023

Signed:

ASTAR.
EXPORT DEPARTMENT DIRECTOR
Łukasz Gajewski

ASTAR
Spółka z ograniczoną odpowiedzialnością
Swit Street 33 43-382 BIELSKO-BIAŁA
Poland
TIN PL5472113926
tel. +48 33 827 18 56 tel. +48 33 827 18 69