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. 1 din 18.09.2023

Solicitantul „GBG-MLD" SRL, cu sediul în mun. Chişinău, 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 şi punerea la dispoziţie pe piaţă a producatorului **ASTAR,**

Nr	Denumirea Generica	Clasa
1	Vacuum Therapy unit Avaco	IIa
2	Therapeutic lamp Lumina, version 5.0	IIa
3	Multifunctional unit PhysioGo 100A	IIa
4	Multifunctional unit PhysioGo 101A	IIa
5	Multifunctional unit PhysioGo 200A	IIa
6	Multifunctional unit PhysioGo 201A	IIa
7	Multifunctional unit PhysioGo 300A	IIa
8	Multifunctional unit PhysioGo 301A	IIa
9	Electrotherapy unit PhysioGo.Lite Electro	IIa
10	Ultrasound therapy unit PhysioGo.Lite Sono	IIa
11	Low frequency magnetic field therapy unit Physio MG 827	IIa
12	Low frequency magnetic field therapy unit Physio MG 825	IIa
13	Low frequency magnetic field therapy unit Physio MG 815	IIa

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.12 15:06:37 EET
Reason: MoldSign Signature
Location: Moldova

Data 18.09.2023

Semnătura

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L. "GBG-MLD" Nr.6
IDNO 1003600117562
REPUBLICA MOLDOVA, MUN. CHIŞINĂU

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	

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. 1 din 18.09.2023

Solicitantul „GBG-MLD" SRL, cu sediul în mun. Chişinău, 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 şi punerea la dispoziţie pe piaţă a producatorului **ASTAR,**

Nr	Denumirea Generica	Clasa
1	Vacuum Therapy unit Avaco	IIa
2	Therapeutic lamp Lumina, version 5.0	IIa
3	Multifunctional unit PhysioGo 100A	IIa
4	Multifunctional unit PhysioGo 101A	IIa
5	Multifunctional unit PhysioGo 200A	IIa
6	Multifunctional unit PhysioGo 201A	IIa
7	Multifunctional unit PhysioGo 300A	IIa
8	Multifunctional unit PhysioGo 301A	IIa
9	Electrotherapy unit PhysioGo.Lite Electro	IIa
10	Ultrasound therapy unit PhysioGo.Lite Sono	IIa
11	Low frequency magnetic field therapy unit Physio MG 827	IIa
12	Low frequency magnetic field therapy unit Physio MG 825	IIa
13	Low frequency magnetic field therapy unit Physio MG 815	IIa

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

Data 18.09.2023

Semnătura _____

SOCIETATE CU RĂSPUNDERE LIMITATĂ "GBG-MLD" S.R.L. Nr.6 IDNO 1003609117582 REPUBLICA MOLDOVA, MUN. CHIŞINĂU

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	

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 declarații, că documentele și datele furnizate pentru înregistrarea dispozitivelor producătorului **ASTAR** pentru introducerea și punerea la dispoziție pe piață a următoarelor produse:

Nr	Denumirea Generica	Clasa
1	Vacuum Therapy unit Avaco	IIa
2	Therapeutic lamp Lumina, version 5.0	IIa
3	Multifunctional unit PhysioGo 100A	IIa
4	Multifunctional unit PhysioGo 101A	IIa
5	Multifunctional unit PhysioGo 200A	IIa
6	Multifunctional unit PhysioGo 201A	IIa
7	Multifunctional unit PhysioGo 300A	IIa
8	Multifunctional unit PhysioGo 301A	IIa
9	Electrotherapy unit PhysioGo.Lite Electro	IIa
10	Ultrasound therapy unit PhysioGo.Lite Sono	IIa
11	Low frequency magnetic field therapy unit Physio MG 827	IIa
12	Low frequency magnetic field therapy unit Physio MG 825	IIa
13	Low frequency magnetic field therapy unit Physio MG 815	IIa

Sunt autentice și corespund realității.

Cristina GUȚU, Șef Secție „GBG-MLD" SRL

Semnătura _____

Data _____

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date June 22, 2021

Astar Spółka z Ograniczona Odpowiedzialnością
ul. Świt 33
43-382 Bielsko-Biała
Poland

"To Whom It May Concern",

In reference to the EC certificate number HD 1962094-1 hereby we confirm that following products listed below:

- Laser therapy unit PhysioGo.Lite Laser, class IIb;
- Laser therapy unit Polaris 2, class IIb;
- Laser therapy unit Polaris HP S, class IIb;
- Laser therapy unit Polaris HP M, class IIb;
- Multifunctional unit PhysioGo 701I, class IIb;
- Multifunctional unit PhysioGo 701C, class IIb;
- Multifunctional unit PhysioGo 601C, class IIb;
- Multifunctional unit PhysioGo 501I, class IIb;
- Multifunctional unit PhysioGo 500I, class IIb;
- Multifunctional unit PhysioGo 401C, class IIb;
- Multifunctional unit PhysioGo 400C, class IIb;
- Multifunctional unit PhysioGo 301A, class IIa;
- Multifunctional unit PhysioGo 300A, class IIa;
- Multifunctional unit PhysioGo 201A, class IIa;
- Multifunctional unit PhysioGo 200A, class IIa;
- Multifunctional unit PhysioGo 101A, class IIa;
- Multifunctional unit PhysioGo 100A, class IIa;
- Multifunctional unit PhysioGo 600C, class IIb;
- Multifunctional unit PhysioGo 700C, class IIb;
- Multifunctional unit PhysioGo 700I, class IIb;
- Multifunctional unit Etius ULM, class IIb;
- Multifunctional unit Etius LM, class IIb;
- Electrotherapy unit Etius, class IIa;
- Electrotherapy and ultrasound therapy unit Etius U, class IIa;
- Electrotherapy unit PhysioGo.Lite Electro, class IIa;
- Ultrasound therapy unit Sonaris S, class IIa;
- Ultrasound therapy unit Sonaris M, class IIa;
- Ultrasound therapy unit PhysioGo.Lite Sono, class IIa;
- Vacuum therapy unit Avaco, class IIa;
- Therapeutic lamp Lumina, version 5.0, class IIa;
- Shock wave physiotherapy unit Impactis M+, class IIb;
- Shock wave physiotherapy unit Impactis M, class IIb;
- Low frequency magnetic field therapy unit Physio MG 827, class IIa;
- Low frequency magnetic field therapy unit Physio MG 825, class IIa;
- Low frequency magnetic field therapy unit Physio MG 815, class IIa;

are covered by the scope of certification.
Best regards,

J. Pyclik

Jarosław Pyclik
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

DECLARATION OF CONFORMITY no 12/19/DC/VC/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33**
43-382, Bielsko-Biała, Poland

Product name:

Vacuum therapy unit
Avaco

Classification:
Vacuum therapy unit Avaco with accessories:

- class IIa rule 9 – for vacuum therapy function

Declaration:
Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:
Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form VC-KBK, version 2.0, updated on 12.02.2020.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 04/19/DC/LU5/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33**
43-382, Bielsko-Biała, Poland

Product name:

Therapeutic lamp Lumina
version 5.0

Classification:
Therapeutic lamp Lumina with accessories:

- class IIa rule 9

Declaration:
Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:
Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form LU5-KBK, version 2.0, updated on 12.02.2020.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 02/20/DC/PHG1/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33,**
43-382, Bielsko-Biała, Poland

Product name:

Multifunctional unit PhysioGo 100A / 101A

Classification:
Multifunctional unit PhysioGo 100A / 101A with accessories:

- **class IIa according to rule 9**

Declaration:
Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:
Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form PHG-KBK, version 3.0, dated on 06.11.2020.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 03/20/DC/PHG2/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33,**
43-382, Bielsko-Biała, Poland

Product name:

Multifunctional unit PhysioGo 200A / 201A

Classification:

Multifunctional unit PhysioGo 200A / 201A with accessories:

- GSW-4/1 type ultrasound head
- GSW-1/1 type ultrasound head
- **class IIa according to rule 9**

Declaration:

Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:

Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form PHG-KBK, version 3.0, dated on 06.11.2020.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 04/20/DC/PHG3/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33,**
43-382, Bielsko-Biała, Poland

Product name:

Multifunctional unit PhysioGo 300A / 301A

Classification:

Multifunctional unit PhysioGo 300A / 301A with accessories:

- GSW-4/1 type ultrasound head
- GSW-1/1 type ultrasound head

- **class IIa according to rule 9**

Declaration:

Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:

Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form PHG-KBK, version 3.0, dated on 06.11.2020.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 03/21/DC/PLE/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33**
43-382, Bielsko-Biała, Poland

Product name:

Electrotherapy unit PhysioGo.Lite Electro

Classification:
Electrotherapy unit PhysioGo.Lite Electro with accessories:

- Electrotherapy patient's cables
- Power supply, compatible types Sinpro HPU63B-108, Mean Well GSM60B24-P1J

- **class IIa according to rule 9**

Declaration:
Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:
Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form PLE-KBK, version 1.0, updated on 19.05.2021.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 04/21/DC/PLS/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33**
43-382, Bielsko-Biała, Poland

Product name:

Ultrasound therapy unit PhysioGo.Lite Sono

Classification:
Ultrasound therapy unit PhysioGo.Lite Sono with accessories:

- GU-1 type ultrasound head
- GU-5 type ultrasound head
- SnG type ultrasound head
- Power supply, compatible types Sinpro HPU63B-108, Mean Well GSM60B24-P1J

- **class IIa according to rule 9**

Declaration:
Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:
Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests card" form PLS-KBK, version 1.0, updated on 19.05.2021.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

DECLARATION OF CONFORMITY no 05/19/DC/PMG/EN/SPZOO

Manufacturer: **Astar Spółka z Ograniczoną Odpowiedzialnością**

Address: **ul. Świt 33,**
43-382, Bielsko-Biała, Poland

Product name:

Low frequency magnetic field therapy unit PhysioMG

Models list:

- **815**
- **825**
- **827**

Classification:

Low frequency magnetic field therapy unit PhysioMG with accessories:

- CP and CPEP type magnetic field plane applicators
- CS35, CS60 and CS75 type magnetic field solenoid applicators
- ST_CS type trolley for magnetic field applicators
- LE_CS type couch for magnetotherapy

- **class IIa, rule 9 – for low frequency magnetic field therapy function**

Declaration:

Manufacturer declares under his own responsibility that the product described above complies with the requirements of the Council Directive 93/42/EEC for medical devices, which apply to it.

Conformity assessment procedure:

Annex II (chapter 4 of Annex II is not applicable) of EC Directive 93/42/EEC.

This statement of conformity is valid in connection with the release document for the respective unit of produced devices – „Final tests report and completion form" form PMG-KBK, version 1.0, dated on 29.06.2018.

EC certificate: HD 1962094-1
QMS certificate: SX 1962094-1

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg, Germany

CE
0197

Bielsko-Biała, Poland, 24.05.2021
(place and date of issue)

Robert Dziendziel, Member of the Board
(name and function)

signature:

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 56/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Vaccum therapy unit Avaco	-

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (*OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices
Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland, Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 54/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Therapeutic lamp Lumina Version 5.0	-

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (*OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland. Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 60/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Multifunctional unit PhysioGo	Models: 100A, 101A

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *(OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices
Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 59/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Multifunctional unit PhysioGo	Models: 200A, 201A

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *(OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 58/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Multifunctional unit PhysioGo	Models: 300A, 301A

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *(OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland, Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 52/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Electrotherapy unit PhysioGo.Lite Electro	-

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC *(OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland, Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 51/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Ultrasound therapy unit PhysioGo.Lite Sono	-

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (*OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warsaw, 2023-02-07

CERTIFICATE OF FREE SALE No. 53/2023

In reference to application for a free sale certificate made by the

Astar Spółka z ograniczoną odpowiedzialnością
(applicant for certificate of free sale)

it is concluded that the medical device listed below:

Name of the device	Type
Magnetotherapy unit PhysioMG	Models: 815, 825, 827

manufactured by:

Astar Spółka z ograniczoną odpowiedzialnością
Ul. Świt 33, 43-382 Bielsko-Biała, Poland
(identification of the manufacturer)

on the basis of the statement of the manufacturer the aforementioned medical device is CE marked at the sole responsibility of the manufacturer. Medical device marked with the CE mark for conformity with the requirements of the Act on Medical Devices of 20th May 2010 (O.J. of 2021, item 1565) which implements Directive 93/42/EEC may be placed on the market or put into service in the territory of Republic of Poland in accordance with art. 120.3 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (*OJ L 117, 5.5.2017, p. 1)* until 26 May 2024. The export of the above-mentioned product is not prohibited.

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski

Certificate of Free Sale is issued pursuant to the provisions of the art. 138.6 of the Act on Medical Devices of 7th April 2022 (O.J., item 974)

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

Nr	Denumirea Generica	Clasa
1	Vacuum Therapy unit Avaco	IIa
2	Therapeutic lamp Lumina, version 5.0	IIa
3	Multifunctional unit PhysioGo 100A	IIa
4	Multifunctional unit PhysioGo 101A	IIa
5	Multifunctional unit PhysioGo 200A	IIa
6	Multifunctional unit PhysioGo 201A	IIa
7	Multifunctional unit PhysioGo 300A	IIa
8	Multifunctional unit PhysioGo 301A	IIa
9	Electrotherapy unit PhysioGo.Lite Electro	IIa
10	Ultrasound therapy unit PhysioGo.Lite Sono	IIa
11	Low frequency magnetic field therapy unit Physio MG 827	IIa
12	Low frequency magnetic field therapy unit Physio MG 825	IIa
13	Low frequency magnetic field therapy unit Physio MG 815	IIa