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

Către Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____din _____

Solicitantul Pharmony S.R.L., cu sediul în mun.Chișinău, or.Durlești, str.Durlești, 4, tel: 0 696 46 604, 0 799 844 01, e-mail info@pharmony.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:

Nr.	Denumire	Modelul	Tara	Producător
1	Sistem ECG de repaus și stres	CardioPart 12 Blue	Germania	AMEDTEC Medizintechnik Aue GmbH

Se anexează următoarele acte:
1. Scrisoarea de autorizare de la producător;
2. Declarația de conformitate CE;
3. Certificat de conformitate CE;
4. Declarația pe proprie răspundere;
5. Lista dispozitivelor medicale supuse modificării.

Alexandru Șarco
Director

Digitally signed by Șarco Alexandru
Date: 2023.07.14 08:35:48 EEST
Reason: MoldSign Signature
Location: Moldova

Semnătura _____

Data

Tabelul de recepționare a notificării

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 Dispozitivelor Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: Pharmony SRL, cu sediul în mun.Chișinău, or.Durlești, str. Durlești, 4,

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 notificarea următoarelor dispozitive medicale (*Producător* – AMEDTEC Medizintechnik Aue GmbH

Nr.	Denumire	Modelul	Tara	Producător
1	Sistem ECG de repaus și stres	CardioPart 12 Blue	Germania	AMEDTEC Medizintechnik Aue GmbH

Sunt autentice și corespund realității.

Alexandru Șarco
Director

Semnătura _____

Data

WEIL DER MENSCH ZÄHLT.

AMEDTEC
Medizintechnik Aue GmbH

AMEDTEC Medizintechnik Aue GmbH · Schneeberger Str. 5 · 08280 Aue

Schneeberger Straße 5 · 08280 Aue
Telefon +49 (0)3771 59 827-0
Telefax +49 (0)3771 59 827-90
www.amedtec.de · info@amedtec.de

Gartenstraße 36 · 97616 Bad Neustadt
Telefon +49 (0)9771 6315500

Geschäftsführer
Daniel Schrödter
Johanna Genberg

Amtsgericht Chemnitz
HRB 15207
USt-IdNr. DE192533073
Steuer-Nr. 218/105/03251

Bankverbindung
Volksbank Chemnitz eG
IBAN DE94 8709 6214 0321 0528 00
BIC GENODEF1CH1

DB Privat- und Firmenkundenbank
IBAN DE14 8707 0024 0416 2772 00
BIC DEUTDEDBCHE

Aue, 22nd of June 2023

Letter of Authorization

We,
AMEDTEC Medizintechnik Aue GmbH
Schneeberger Strasse 5
08280 Aue
Germany

as the manufacturer of the medical devices 12-lead Stress Test ECG systems, Resting ECG and Holter ECG,

including all the articles mentioned in the Declaration of Conformity attached to this submission, hereby authorize

Pharmony S.R.L. – 4
Durlesti Str.
Chisinau, MD2071
Republic of Moldova

as the representative, Importer and Distributor, to prepare and submit applications for the evaluation and registration of the abovementioned medical devices to the Competent Authorities on our behalf.

This authorization shall remain in effect until our notification to the Competent Authorities in writing (either by postal mail, e-mail or facsimile transmission) that it is revoked – subject to any conditions imposed by the Competent Authorities.

We undertake to provide all the necessary support and assistance to the representative as may be required in relation to any matter involving the above mentioned medical devices. We agree to provide and assist the competent authorities with any request for information on the above mentioned medical devices.

The authorization is valid for 12 month.

Joachim Noethling
Manager Sales and Marketing
AMEDTEC Medizintechnik Aue GmbH

SLG Prüf- und
Zertifizierungs GmbH

EG-Zertifikat
EC Certificate

Vollständiges Qualitätssicherungssystem
Full Quality Assurance System

Richtlinie 93/42/EWG für Medizinprodukte, Anhang II ohne Abschnitt 4 (Klasse IIa-Produkte)
Directive 93/42/EEC on Medical devices, Annex II excluding section 4 (Class IIa Devices)

Produkt / Kategorie(n) **Product / Category(ies):**	Geräte und Software zur Herzkreislauf-Diagnostik Equipment and Software for Cardiovascular Diagnostics
eingeschlossene Produkte **Products covered by certificate:**	Elektrokardiographen | Electrocardiographs Langzeit--EKG-Rekorder | Long-Term ECG Recorders Langzeit-EKG-Auswerteeinheit | Long-Term ECG Recording Scanners Kardiologie Informationssysteme | Cardiology Information Systems
Typ Type:	siehe Anlage
UMDNS:	11-411 12-388 15-295
Klassifizierung Classification	IIa
Hersteller **Manufacturer:**	AMEDTEC Medizintechnik Aue GmbH Schneeberger Straße 5 08280 Aue, Deutschland / Germany
Zertifikats-Nr. **Certificate no.:**	110192N2
Gültig ab **Valid from:**	2020-09-02
Gültig bis **Valid until:**	2024-05-26

Die Benannte Stelle 0494 SLG Prüf- und Zertifizierungs GmbH bescheinigt der zuvor genannten Firma die Anwendung eines Qualitätssicherungssystems für Auslegung, Herstellung und Endkontrolle der entsprechenden Produkte / Produktkategorien nach Medizinprodukte-Richtlinie Anhang II.

The Notified Body 0494 SLG Prüf- und Zertifizierungs GmbH declares that the aforementioned company has implemented a quality assurance system for design, manufacturing and final inspection of the respective devices / device categories in accordance with the Medical Device Directive Annex II.

Die Einhaltung der anwendbaren Anforderungen des Anhang II wurde bewertet in:
Compliance with the applicable requirements of Annex II was reviewed in:

Auditabschlussbericht
Final Audit Summary Report: SLG - 5046-19-PP-20-QB002

Das zuvor beschriebene Qualitätssicherungssystem unterliegt der regelmäßigen Überwachung gemäß Anhang II Abschnitt 5.
The quality assurance system described above is subject to periodic surveillance in accordance with Annex II section 5.

Hartmannsdorf, 02.09.2020
SLG file no.: 5046-19-PP

SLG Prüf- und Zertifizierungs GmbH
SLG
ZERTIFIZIERUNGS-STELLE

M. Herrig
Zertifizierungsstelle
Certification Body

SLG Prüf- und Zertifizierungs GmbH
Burgstädter Straße 20
09232 Hartmannsdorf · Germany
Tel.: +49 3722 7323-0
Fax: +49 3722 7323-899
service@slg.de.com
www.slg.de.com

Anlage zu Zertifikat Nr.
Annex to certificate no.: 110192N2

Revision: 0

Hersteller
Manufacturer:

AMEDTEC Medizintechnik Aue GmbH
Schneeberger Straße 5
08280 Aue, Deutschland / Germany

Liste der im Zertifikat enthaltenen Produkte
List of products covered by the certificate

Typ Type	Klassifizierung Classification	UMDNS
CardioPart 12 USB	IIa	11-411
CardioPart 12 Blue	IIa	11-411
CardioPart 12 WLAN	IIa	11-411
CardioPart 12 USB "nomadeec"	IIa	11-411
CardioPart 12 Blue "nomadeec"	IIa	11-411
Holter EP8	IIa	15-295
EP820	IIa	12-388
EP830	IIa	12-388
EP820-12	IIa	12-388
EP830-12	IIa	12-388
Holter-RR	IIa	18-119

SLG Prüf- und Zertifizierungs GmbH
SLG
ZERTIFIZIERUNGS-STELLE

Hartmannsdorf, 02.09.2020
SLG file no.: 5046-19-PP

M. Herrig
Zertifizierungsstelle
Certification Body

EU-Konformitätserklärung

EU – Declaration of Conformity

Wir | *We*	AMEDTEC Medizintechnik Aue GmbH Schneeberger Str. 5 08280 Aue Deutschland | *Germany* SRN: DE-MF-000006859

erklären als Hersteller in alleiniger Verantwortung, dass das Medizinprodukt
declare as the manufacturer under our sole responsibility that the medical device

Produktname | *product name*	**CardioPart 12 Blue**
UMDNS	11-411
der Risikoklasse | *of risk class*	IIa (gem. MDD, Anhang IX Regel 10 | *per MDD, Annex IX, Rule 10*)

in Übereinstimmung mit
Anh. II i.V. m. Anh. VII Abs. 3 der Richtlinie 93/42/EWG (MDD) hergestellt ist,
gemäß Artikel 120 (2) Abs. 2 der Verordnung (EU) 2017/745 (MDR) in Verkehr gebracht wird
und außerdem den einschlägigen Anforderungen der Richtlinien 2014/53/EU (RED) sowie 2011/65/EU (RoHS) i. V. m. den Richtlinien 2017/2102 und 2015/863 entspricht
is manufactured in accordance with Annex II in conj. with Annex VII (3) of Council Directive 93/42/EEC (MDD),
is placed on the market in accordance with Article 120 (2) (2) of Regulation (EU) 2017/745 (MDR),
and also meets the relevant requirements of the directives 2014/53/EU (RED) and 2011/65/EU (RoHS) in conj. with EU directives 2017/2102 and 2015/863

ohne wesentliche Änderungen von Auslegung oder Zweckbestimmung entsprechend der aktuell geltenden Bescheinigung *without significant changes in design or intended use according to the currently valid certificate*	EG-Zertifikatsnr. | *EC Certificate no.*: **110192N2**
ausgestellt und überwacht durch die Benannte Stelle (nur MDD) *issuing and supervising Notified Body* *(only MDD)*	SLG Prüf- und Zertifizierungsstelle GmbH Burgstädter Str. 20 09232 Hartmannsdorf, Deutschland | *Germany* Kennnummer | *identification no*: **0494**
gültig bis | *valid until*	2024-05-26

Aue, 2022-02-11
Ort, Datum \| *place, date*

.....
Geschäftsführer
Managing Director

Die Gültigkeitsdauer der Konformitätserklärung kann sich durch die Ausstellung einer revidierten Konformitätserklärung nach Änderung des Produkts und/oder durch das Ablaufdatum des von der Benannten Stelle ausgestellten EG-Zertifikats ändern.
The validity of the declaration of conformity may be altered by issuing a revised declaration of conformity after the product has been changed and/or by the expiry date of the EC Certificate issued by the Notified Body.