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	Denumire comercială	Modelul	Cod produs	Tara	Producător
1	Ergometru	ERGOLINE	Ergoselect 4, color touch control unit type P	191801	Germania	ergoline 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.

Digitally signed by Șarco Alexandru
Date: 2023.07.14 08:38:02 EEST
Reason: MoldSign Signature
Location: Moldova

Alexandru Șarco
Director Semnătura _____

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* – ergoline GmbH, Germania):

Nr.	Denumire	Denumire comercială	Modelul	Cod produs	Tara	Producător
1	Ergometru	ERGOLINE	Ergoselect 4, color touch control unit type P	191801	Germania	ergoline GmbH

Sunt autentice și corespund realității.

Alexandru Șarco
Director

Semnătura _____

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MOVING TO HEALTH

Letter of Authorization

We,

Ergoline GmbH
Located at Lindenstraße 5, 72475 Bitz, Germany, as the manufacturer of the following medical devices: 12-lead Stress Test ECG systems, Resting ECG, Holter ECG, including all the articles mentioned in the Declaration of Conformity attached to this submission, heberby 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 authorisation 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 authorisation is valid until further notice.

For and on behalf of

Josef de Witt
CEO

ergoline GmbH
Lindenstraße 5 • D-72475 Bitz
Tel.: +49(0)7431 • 9894-0

28.06.2023

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 044463 0022 Rev. 01

Manufacturer: **Ergoline GmbH**
Lindenstr. 5
72475 Bitz
GERMANY

Facility(ies): Ergoline GmbH
Lindenstr. 5, 72475 Bitz, GERMANY

Product Category(ies): **Ergometer, Blood Pressure Measuring Instruments, SpO2 Devices and Medical Software for Rehabilitation and Training**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168681

Valid from: 2020-02-17
Valid until: 2024-05-26

Date, 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EG-KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

CE 0123

Wir / We	**ergoline GmbH** **Lindenstr. 5** **72475 Bitz (Germany)**
erklären in alleiniger Verantwortung, dass das Medizinprodukt / declare on our own responsibility that the medical device	**Ergometer / ergometer**
Serie / series	**Ergoselect 4 mit Artikel-Nr. 191001**/ ergoselect 4 with article no.: 191001 **Ergoselect 5 mit Artikel-Nr. 191002**/ ergoselect 5 with article no.: 191002

Erweiterbar um die Optionen / expandable by options

Bestell-Nr./ order no.:	**Abkürzung en /** abbre.	**Bezeichnung** / description
191813	A	**EKG mit Verstärker** / ECG amplifier
191814	C	**EKG mit Sauganlage** / ECG with suction device
191806	B	**Automatische Blutdruckmessung** / automatic blood pressure measurement
191807	S	**Automatische Messung Sauerstoffsättigung** / automatic SpO2 measurement
191801	P	**Bedieneinheit Ergometrie (Typ "P")** / control unit ergometry (type „P")
191802	T	**Farb-/Touch Bedieneinheit (Typ "T")** / color touch control unit (type „T")
191810	Y	**Bluetooth-Schnittstelle** / bluetooth interface
191811	W	**WLAN-Schnittstelle** / WiFi interface

Mit Zubehör / with accessories

Bestell-Nr./ *order* no.:	**Abkürzung en /** abbr.	**Bezeichnung /** description
705944	Q	**Komfort-Pedalschlaufen** / comfort pedal straps
191803	G	**Sattelhöhen-Verstellung mit Gasdruckfeder** / saddle height adjustment with gas spring
191804	E	**Sattelhöhen-Verstellung mit Motor** / horizontal saddle adjustment
191805	L	**Lenkerhöhen-Verstellung elektrisch** / handlebar height adjustment with motor

mit den Anforderungen der Richtlinie übereinstimmt/ is in conformity with the Directive	**93/42/EWG: Anhang II (ohne 4)** 93/42/EEC: annex II (excluding 4)

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Zertifikatsnummer / Certificate Number	**G1 044463 0022 Rev. 01**
Gültigkeit / Validity	**26.05.2024**
UMDNS-Code / UMDNS-Code	**10383**
Benannte Stelle / Notified Body	**TÜV SÜD Product Service GmbH** **Ridlerstr. 65** **80339 München** **Germany**
Konformitätsbewertungsverfahren / Conformity assessment procedure	**Anhang II (Regel 10)** annex IX / rule 10
Klasse / Class	**IIa**
Klassifizierung nach / Classification according to	**Anhang IX / Regel 10** annex IX / rule 10

Beginn der Gültigkeit / Begin of the validity:
Datum/Date: 15.10.2019

Ort/City:
Bitz den, 2020-11-30

Dr. Lutz Neumann
Geschäftsführer / CEO

ergoline GmbH
Lindenstraße 5 • D-72475 Bitz
Tel.: +49(0)7431 • 9894-0