Anexă
Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. ..... din .....

Solicitantul **IM Vivamed International SRL**, cu sediul or. Chisinau,str.Mircea cel Batrin,16 (adresa)
tel./fax: 022926801, e-mail info@vivamed-int.com,
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:

- Sistem radiografic digital (cu bucky vertcal);

Se anexează următoarele acte:
CE,
Declaratie de Conformitate

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 Belan Irina
Date: 2023.07.01 13:54:24 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant:**IM Vivamed International SRL,** cu sediul in mun.Chisinau,Bd.Mircea cel Batrin,16,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

Sistem radiografic digital (cu bucky vertical);

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia
Director Beregoi Valeriu

Semnătura _____

Data _____

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Sistem radiografic digital (cu bucky vertical)	Nanjing Perlove Medical Equipment Co.	PLD6500A	37645

Director IM Vivamed International SRL
Beregoi Valeriu

PERLOVE MEDICAL

PERLOVE Nanjing Perlove Medical Equipment Co.,Ltd

For presentation to:

Centrul Pentru Achiziţii Publice Centralizate în Sănătate in Rep.Moldova

Number of Bid: 21081293 LOT 1 and 2

Bids submission date: 3 July, 2023

Exclusive Authorization Letter

We, **Nanjing Perlove Medical Equipment Co., Ltd.** located No. 97&99, Wangxi Road, Jiangning District, 211122, Nanjing, China, as the manufacturers of Digital radiography systems, components and accessories, confirm that:

IM Vivamed Internationnal SL, located at Str Bogdan Voievod 7MD-2068 Chişinău city Republic of Moldova, is our official distributor for the territory of Republic of Moldova.

IM Vivamed Internationnal SL is authorized by **Nanjing Perlove Medical Equipment Co., Ltd.** to distribute, promote, service and support our products in the territory of Republic of Moldova.

IM Vivamed Internationnal SL may serve in the participation of private and government tenders, price negotiations and otherwise act as our distributor in such matters to participate in tender 21081293 LOT 1 with our products: **Medical Diagnostic X-ray System, PLD6500A**

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.

We also confirm that:

- Availability of a service engineer & service center on the territory of the Republic of Moldova
- Training of personnel on the operation of this device, 3 employees from the moment of installation of the equipment
- The warranty period 14 months
- We guarantee timely and in the right quantities delivery of goods and also studies of staff by specialists of IM Vivamed Internationnal SL, certificated by us. Authorization letters provided by other participants are considered invalid.

Signed:

Name: Alexey Yu

Title: Sales Manager

[Authorization No:20230626085]

Declaration

To: Whom it concerns

Nanjing Perlove Medical Equipment Co., Ltd was founded in 2003, located in No.97 and 99 Wangxi Road, Jiangning District, Nanjing, P.R.China. Perlove is a high-tech enterprise integrating research and development, production, sales and after-sales services of medical X-ray imaging equipment.

Zhuhai Perlead Medical Equipment Co., Ltd is the subsidiary of Nanjing Perlove Medical Equipment.

Attached is the query information of the National Enterprise Credit Information Publicity System for reference.

Hereby Stated

Nanjing Perlove Medical Equipment Co., Ltd

16th Jun, 2022

Zhuhai Perlead Medical Equipment Co., Ltd

16th Jun, 2022

Add: No.97 and No.99 Wangxi Road, Jiangning District, Nanjing,P.R.China

Tel:025-68571666, E-mail: info@perlove.com.cn

www.perlove.cn

TÜV Rheinland (China) Ltd.

TÜVRheinland®
Precisely Right.

TÜV Rheinland (China) Ltd.

Tel.: +86-10-6556 66660
Fax: +86-10-6556 66667
Mail: info@bj.chn.tuv.com
Web: www.chn.tuv.com

Beijing, April 27, 2020

To whom it may concern:

This is to confirm for the full quality assurance system ---MDD 93/42/EEC Annex II excluding section 4 certificate

Manufacturer: **Zhuhai Perlead Medical Equipment Co., Ltd.**
Address: No. 8877, Zhuhai Road, Pingsha Town,
Jinwan District, Zhuhai, 519090, Guangdong, China
Scope: Medical Diagnostic X-Ray Equipment
Registration No.: HD 60146933 0001

for the following information concerning the products listed as follows:

Name of the Products:	**Models:**
Medical Diagnostic X-Ray Equipment	PLD6500A, PLD6500B, PLD6500C

Kind regards,

Ms. CHEN Yuhong
Manager
Medical Products

TUVR-CL-20200427

TÜV Rheinland (China) Ltd.

TÜV Rheinland Group,

Unit 707, AVIC Bldg., No. 10B,
Central Road, East 3rd Ring
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Web: www.chn.tuv.com

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	Zhuhai Perlead Medical Equipment Co., Ltd. No. 8877, Zhuhai Road, Pingsha Town, Jinwan District, Zhuhai, 519090, Guangdong, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	Digital Radiography X-Ray System
der Klasse: / of class: / de la classe: / di classe:	IIb, GMDN code 37645

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità:	Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4 Directive 93/42/EEC Annex II, excluding Section 4 Directive 93/42/CEE Annexe II, hors section 4 Direttiva 93/42/CEE senza Allegato II, sezione 4
Registrier-Nr.: / Registration No.: / N°d'enregistrement: / Numero di registrazione:	HD 60146933 0001
Expiry Date:	2024-05-26
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland CE 0197

Nürnberg, 2.13

Ort, Datum / Place, date / Lieu, date / Luogo, data

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2054060-1
Organization:	Zhuhai Perlead Medical Equipment Co., Ltd. No. 8877, Zhuhai Road, Pingsha Town, Jinwan District, Zhuhai, 519090 Guangdong P.R. China
Scope:	Design and Development, Manufacture and Distribution of Medical Diagnostic X-Ray Equipment

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	190143215-110
Effective date:	2023-02-06
Expiry date:	2026-02-05
Issue date:	2023-02-03

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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