

Anexă
Către
Agenția Medicamentului
și 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
și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- Sistem radiodiagnostic cu brat C;
- Se anexează următoarele acte:
Certificat CE, ISO
Declaratie de Conformitate,
Autorizatie de la producator.

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	



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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

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

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Sistem radiodiagnostic cu brat C ;
Sunt autentice și corespund realității.

Numele, prenumele și funcția
Director Beregoi Valeriu

Semnătura



Data _____

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Sistem radiodiagnostic cu brat C	Nanjing Perlove Medical Equipment Co.	PLX112B	37645

Director IM Vivamed International SRL
Beregoi Valeriu



Manufacturer's Authorization

Issue Date: 26th, June, 2023

To: Whom May It Concerns

We, Nanjing Perlove Medical Equipment Co., Ltd, having its place of business at No.97, Wangxi Road, Jiangning District, Nanjing, 211122, China, is a manufacturer of the Medical Equipment.

Hereby appoint and authorize:

Company name: IM Vivamed Internationnal SL

Address: Str Bogdan Voievod 7MD-2068 Chişinău city Republic of Moldova

Tel/Fax: +373 691 28 478

As one of the distributors for the products manufactured by our company from the date signed within the territory of **Republic of Moldova**.

IM Vivamed Internationnal SL supplies to register, bid, distribute, supply, install, repair, service, maintenance and provide operational training of our products during the period of validity according to our general business terms and conditions.

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.

In this regard we will extend our full support to **IM Vivamed Internationnal SL** and provide necessary facilities for its marketing and sales promotions. Also we agree to support **IM Vivamed Internationnal SL** with full spare parts and technical support at any time.

The letter is valid until 31st, December, 2023

For & On behalf of :

Nanjing Perlove Medical Equipment Co., Ltd.

Authorized Signatory:

[Authorization No:20230626085]

Certificate



Quality Management System
EN ISO 13485:2016

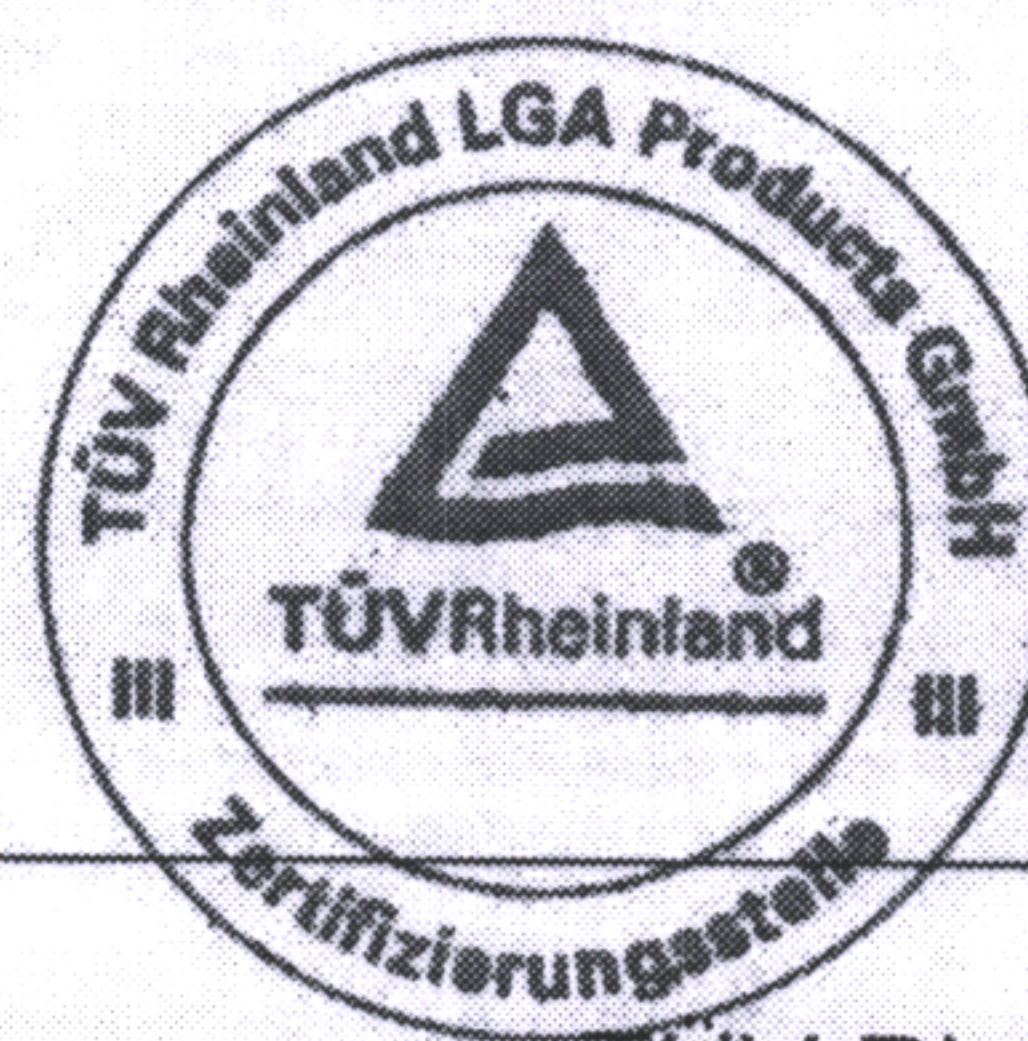
Registration No.: SX 2027461-1

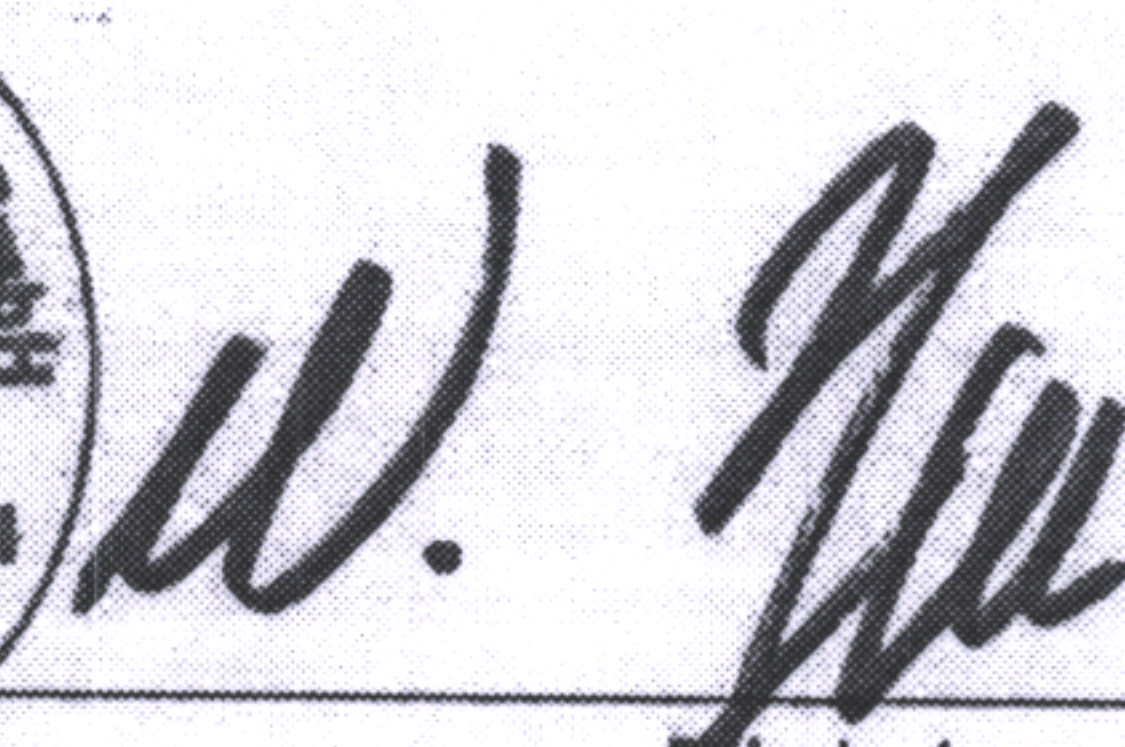
Organization: Nanjing Perlove Medical Equipment
Co., Ltd.
No. 97 and No. 99 Wangxi Road,
Jiangning District, Nanjing,
211100 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of X-ray Imaging
Systems

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.: 244330566-200
Effective date: 2021-08-09
Expiry date: 2024-08-08
Issue date: 2021-08-09




Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Certificate



Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2027461-1

Manufacturer: Nanjing Perlove Medical Equipment
Co., Ltd.
No. 97 and No. 99 Wangxi Road,
Jiangning District, Nanjing,
211100 Jiangsu
P.R. China

Products: Diagnostic X-ray System

Replaces Approval, Registration No.: HD 60130054 0001

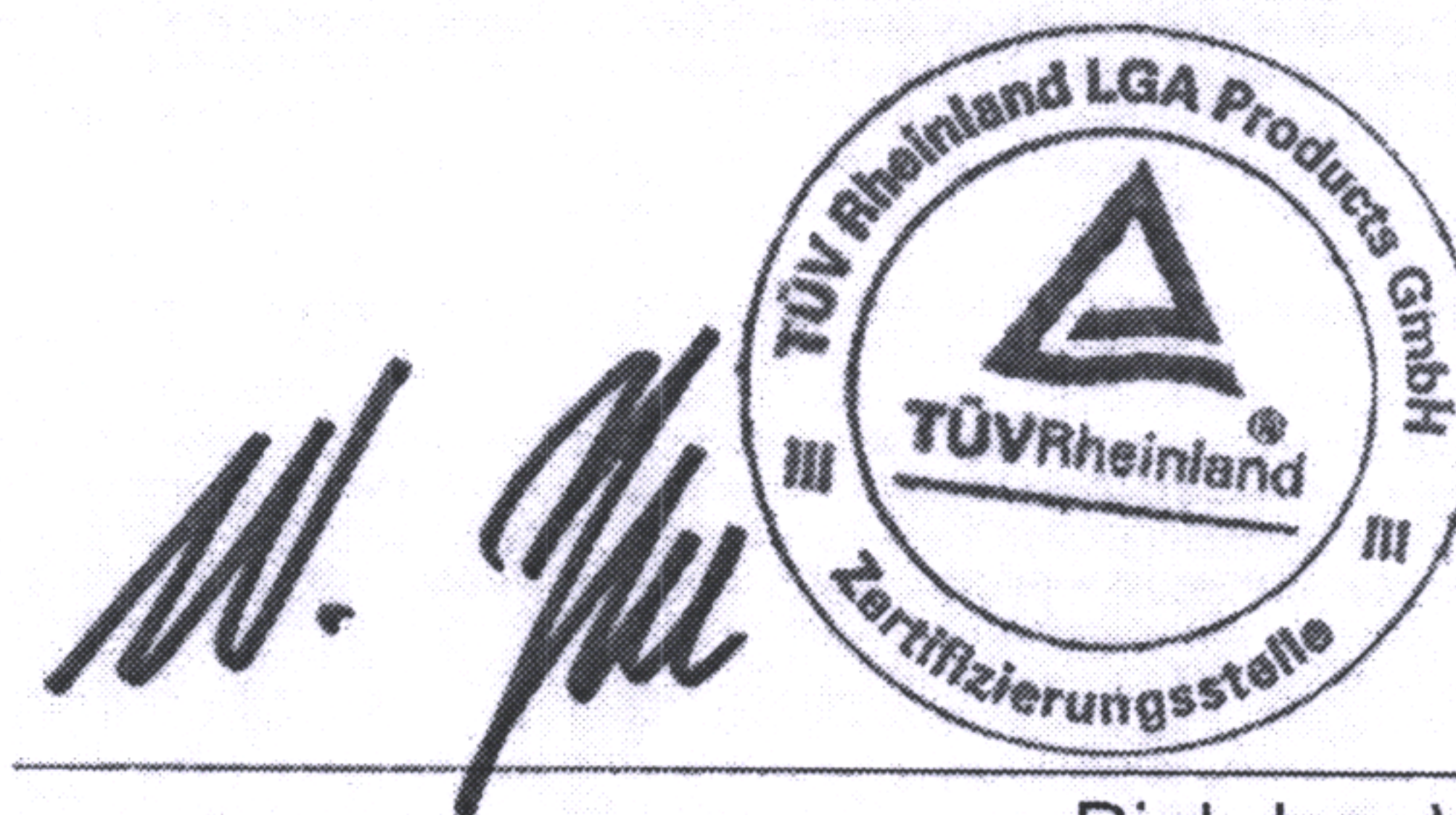
The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 15094128 011

Effective date: 2021-03-25

Expiry date: 2024-05-26

Issue date: 2021-03-25



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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



Name und Adresse des Herstellers: / **Nanjing Perlove Medical Equipment Co., Ltd.**
Name and address of the manufacturer: / **No. 97 and No. 99 Wangxi Road, Jiangning District, Nanjing,**
Nom et adresse du fabricant: / **211100 Jiangsu, P.R. China**
Nome e indirizzo del fabbricante:
European Representative: **Caretechion GmbH**
Address: **Niederrheinstr. 71, 40474 Duesseldorf, Germany**

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: / **Diagnostic X-ray System**
the medical device: / **PLX5100, PLX5200A, PLX112B, PLX118F**
le dispositif médical: /
il dispositivo medico:

der Klasse: / **IIB**
of class: /
de la classe: /
di classe:

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: / **Directive 93/42/EEC Annex II, excluding Section 4**
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Registrier-Nr.: / **HD 2027461-1**
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:
Expiry Date: **2024-05-26**

Benannte Stelle: / **TÜV Rheinland LGA Products GmbH**
Notified Body: / **Tillystraße 2**
Organisme notifié: / **90431 Nürnberg**
Organismo notificato: **Deutschland**
CE 0197

Nanjing 2021-05-17

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

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