

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 radiografic digital (cu bucky vertical);

Se anexează următoarele acte:

CE,

Declarație 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	

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 radiografic digital (cu bucky vertical);
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 radiografic digital (cu bucky vertical)	Nanjing Perlove Medical Equipment Co.	PLD6500A	37645

Director IM Vivamed International SRL
Beregoi Valeriu



For presentation to:

Centrul Pentru Achiziții 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 Chișinău 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]



PERLOVE MEDICAL

Nanjing Perlove Medical Equipment Co., Ltd

Declaration

To: Whom it concerns

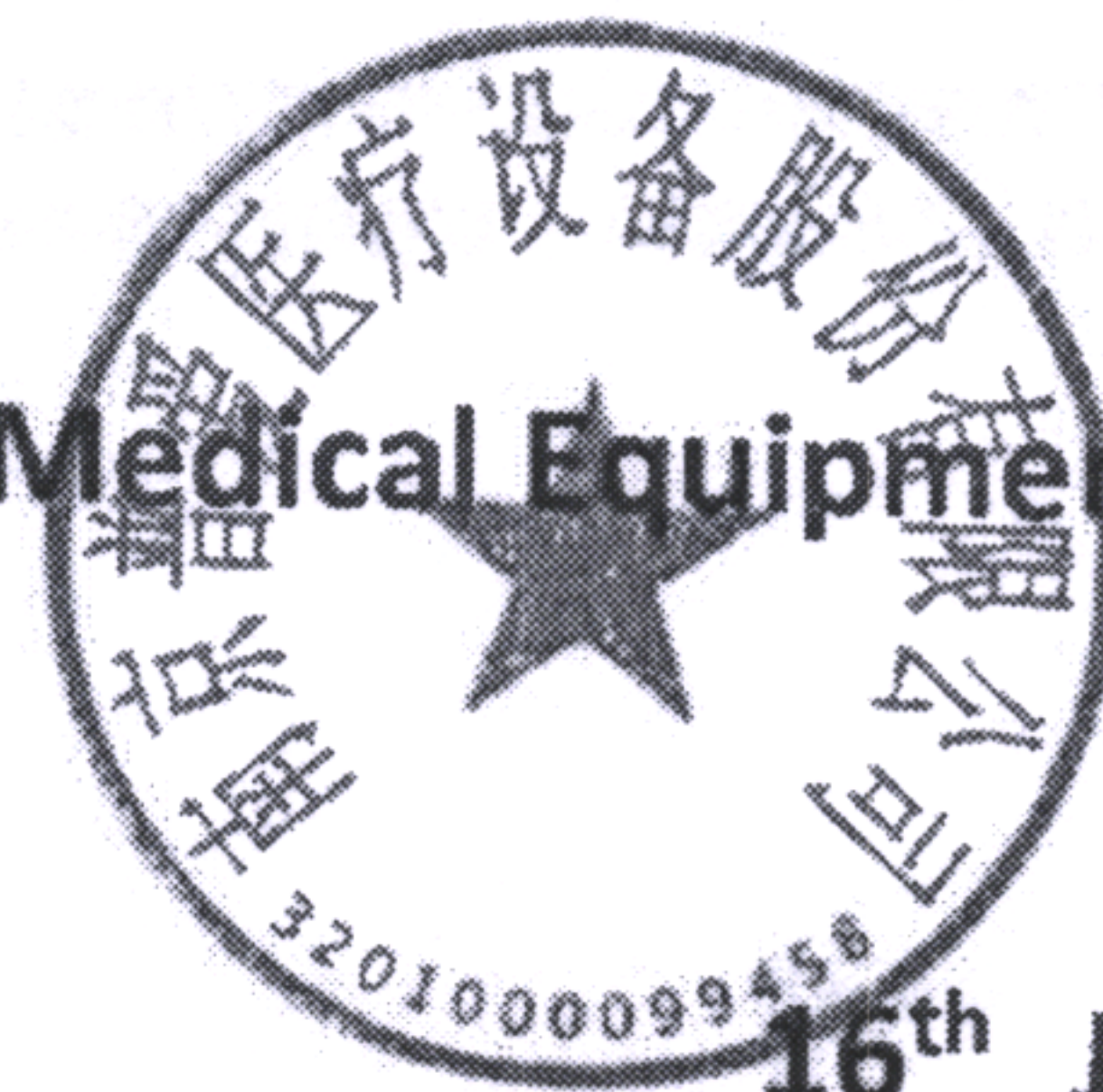
Nanjing Perlove Medical Equipment Co., Ltd was founded in 2003, located in No.97 and 99 Wangxi Road, Jiangning District, Nanjing, P.R.China. Perlove is a high-tech enterprise integrating research and development, production, sales and after-sales services of medical X-ray imaging equipment.

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.

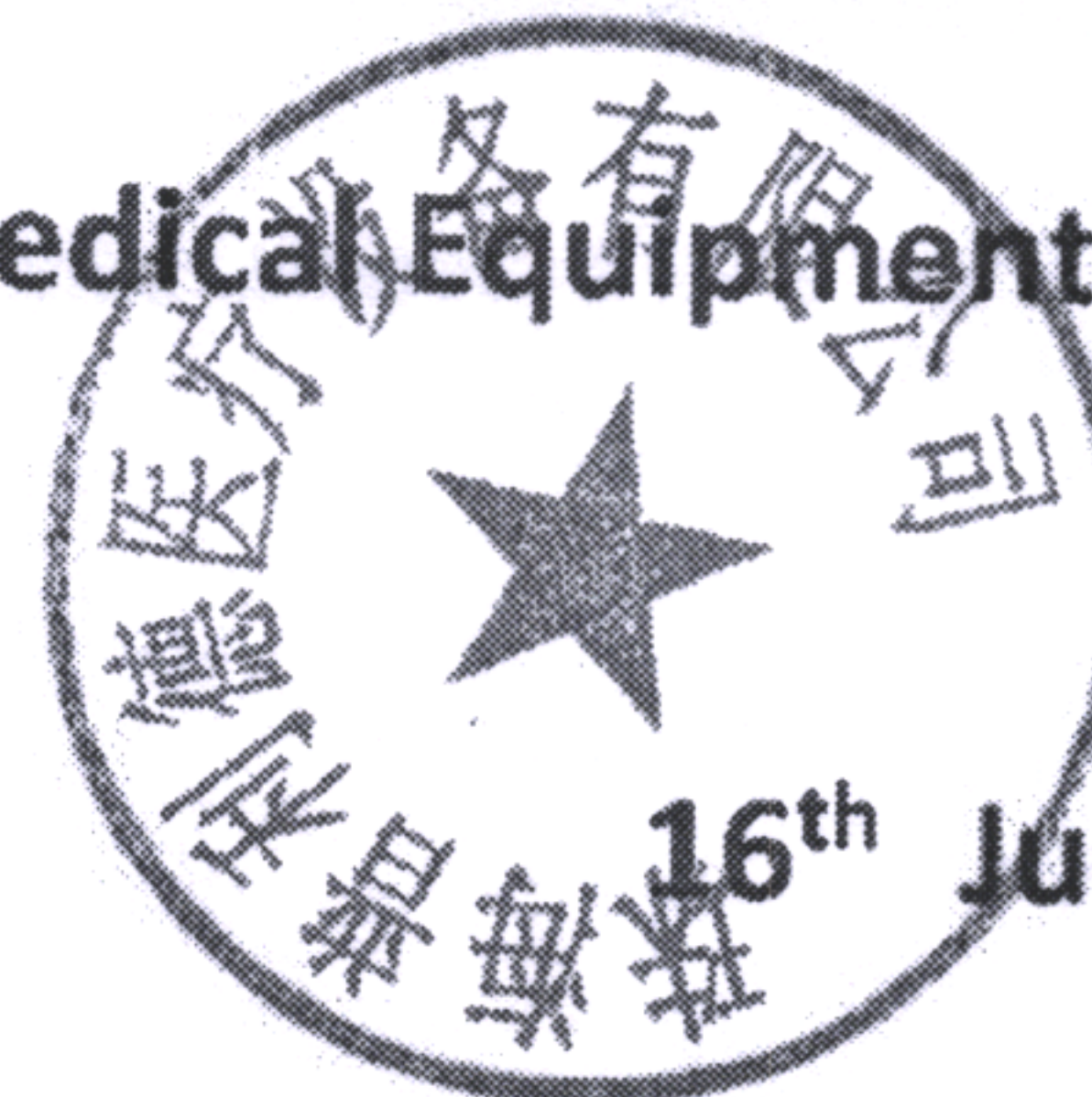
Hereby Stated

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.



TÜV Rheinland (China) Ltd.

Tel.: +86-10-6556 6660
Fax: +86-10-6556 6667
Mail: info@bj.chn.tuv.com
Web: www.chn.tuv.com

To whom it may concern:

Beijing, April 27, 2020

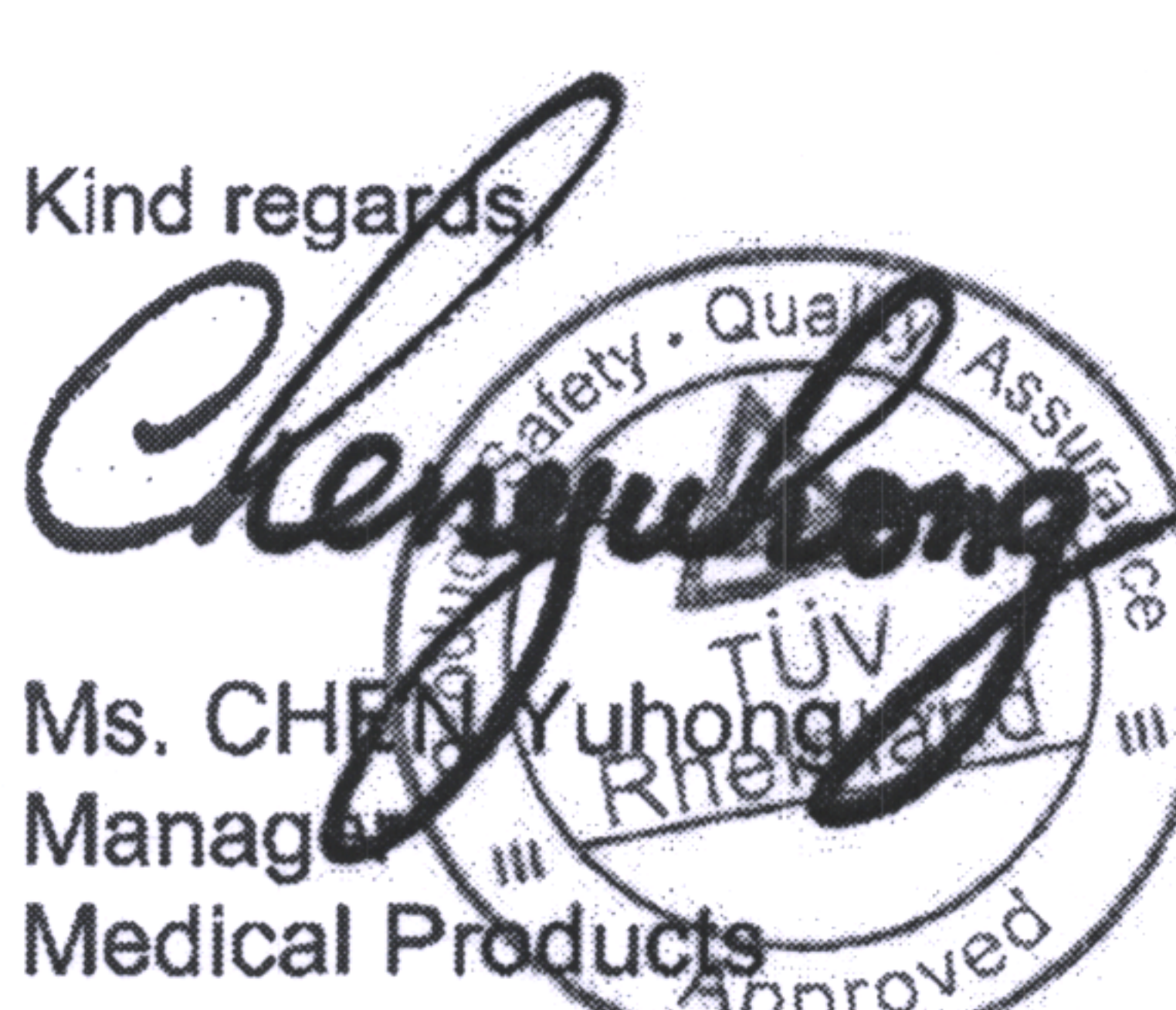
This is to confirm for the full quality assurance system ---MDD 93/42/EEC
Annex II excluding section 4 certificate

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:

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

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: / Digital Radiography X-Ray System
le dispositif médical: /
il dispositivo medico:

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.

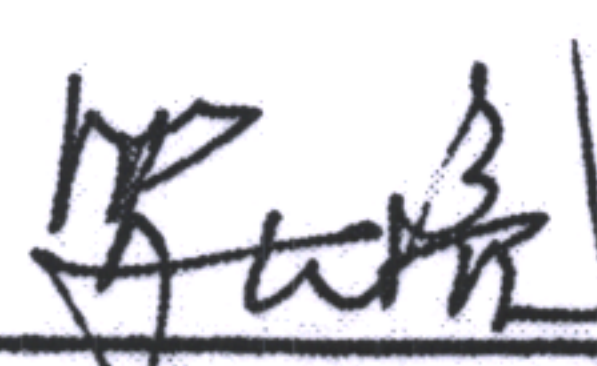
Konformitätsbewertungsverfahren: / Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4
Conformity assessment procedure: / Directive 93/42/EEC Annex II, excluding Section 4
Procédure d'évaluation de la conformité: / Directive 93/42/CEE Annexe II, hors section 4
Procedura di valutazione della conformità: / Direttiva 93/42/CEE senza Allegato II, sezione 4

Registrier-Nr.: / HD 60146933 0001
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

2023. 2. 13

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



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

Certificate



**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



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

