

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:

- Termometru digital;

Se anexează următoarele acte:

EC Certificat,

Declaratie de Conformitate

Authorization

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	

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:

Termometru digital;

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		Termometru digital	Joytech Healthcare Co.Ltd	25557	

Director IM Vivamed International SRL
Beregoi Valeriu



Gessate, 20 December 2022

Authorization for distribution

To whom it may concern

WHEREAS GIMA SPA who are established and reputable manufacturers or distributors of **medical devices** having factories in **Via Marconi 1, 20060 Gessate (MI) - ITALY**

do hereby authorize **VIVAMED** to distribute our products on market of Moldova.
This authorization is valid up to December 2023, and can be renewed.

GIMA S.p.A.
Export Director
Giulio Manzoni



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60147728 0001

Report No.: 15095961 011

Manufacturer: JOYTECH Healthcare Co., Ltd.
No. 365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Products:

- Digital Thermometers
- Blood Pressure Monitors
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers
- Electric Breast Pumps

Replaces Approval, Registration No.: DD 60128148 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-04-07

Date: 2020-04-07

Notified Body

Jason Pan



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



Certificate

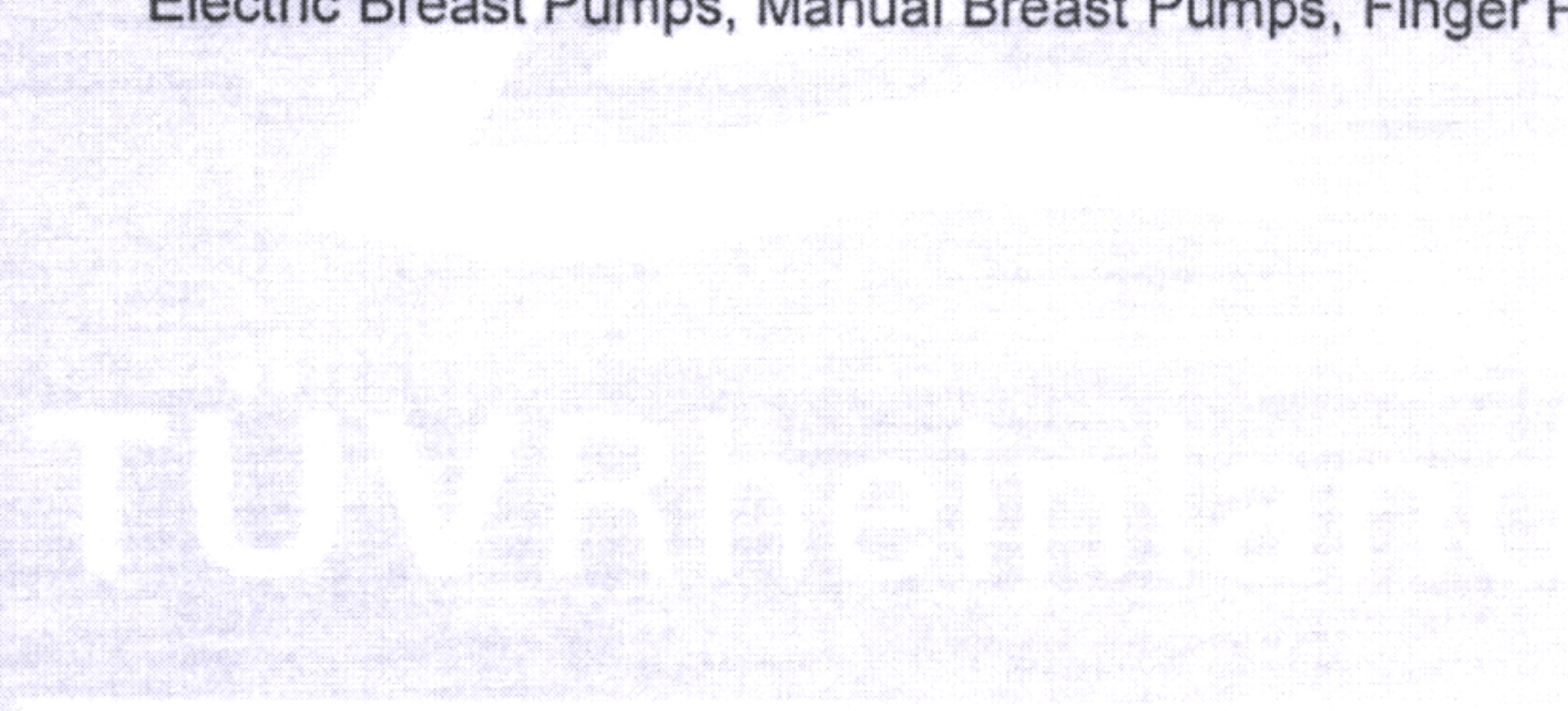


Quality Management System
EN ISO 13485:2016

Registration No.: SX 2018581-1

Organization: JOYTECH Healthcare Co., Ltd.
No. 365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of Digital Thermometers, Blood Pressure Monitors, Infrared Ear Thermometers, Infrared Forehead Thermometers, Infrared Ear/Forehead Thermometers, Electric Breast Pumps, Manual Breast Pumps, Finger Pulse Oximeter



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.: 244410547-200
Effective date: 2022-07-11
Expiry date: 2025-07-10
Issue date: 2022-06-28



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



EC Declaration of Conformity

Manufacturer:

JOYTECH HEALTHCARE CO., LTD.

Address: No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100 Zhejiang, China

whose single Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

Digital Thermometer

Model: DMT-4220

UMDNS-Code: 14035

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa by rule 10 according to Annex IX of the Directive 93/42/EEC.

It bears the mark



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD60147728 0001

Issue date: 2020-04-07

Expiry date: 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: JOYTECH HEALTHCARE CO., LTD.

Address: No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100 Zhejiang, China

Hangzhou, Apr 7th, 2020

Place, date

JO-DMT00-04

Version: A/3


General Manager

Legally binding signature function

