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:

Cintar mecanic pentru nou nascuti;

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia
Director Beregoi Valeriu

Semnătura _____

Data _____

Digitally signed by Belan Irina
Date: 2023.07.01 19:32:19 EEST
Reason: MoldSign Signature
Location: Moldova

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:

Cintar mecanic pentru nou nascuti;

Se anexează următoarele acte:
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	

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1		Cintar mecanic pentru nou nascuti	Fazzini	S 725	

Director IM Vivamed International SRL
Beregoi Valeriu

FAZZINI
Your Health is Our Aim

S.S PADANA SUPERIORE 317 20055 VIMODRONE - ITALY
VAT: IT11626520156 TEL:++39/02/2651521 FAX:++39/02/26515221

REF N.183 /2023

Date 08/06/2023

MESSERS:
COMPANY: TO WHOM IT MAY CONCERN
ADDRESS:
CITY:
AREA CODE:
COUNTRY: ..
FAX:
TEL.:

att: TO WHOM IT MAY CONCERN

Registration of Medical Devices

We FAZZINI SRL, who are official Manufacturers and Suppliers of MEDICAL EQUIPMENT, having premises at S.S. Padana Superiore 317 20055 Vimodrone (MI) Italy,

Assign IM VIVAMED INTERNATIONAL SL Rep. Of Moldova, Str Bogdan Voievod 7 MD-2068 Chisinau City as authorized representative in correspondence with the conditions of directive 93/42/EEC

We declare that the Company mentioned above is authorized to register, notify, renew or modify the registration of medical devices we supplied in the territory of Republic of Moldova

IM VIVAMED INTERNATIONAL SL is also authorized to promote, sell and distribute our Products (Medical Equipment) in the territory of Republic of Moldova, as well as quote them in Public Tenders.

IM VIVAMED INTERNATIONAL SL is also authorized to install, train, commission and maintain our product, as well as taking care of the After-Sale Service.

This Authorization is valid for 1 year period, with the possibility of mutual extension.

BEST REGARDS
GIANLUCA MALETTI
GENERAL MANAGER

FAZZINI SRL
S.S. PADANA SUPERIORE 317
20090 VIMODRONE (MI)
TEL. 02/2651521 FAX. 02/26515221
VAT. IT11626520156

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S.S. Padana Superiore, 317
20055 Vimodrone (MI) – Italia
info@fazzini.it;
quality@fazzini.eu;
Fax +39 02 265152 21

DICHIARAZIONE DI CONFORMITÀ / DECLARATION OF CONFORMITY

GB

The Company FAZZINI SRL with legal and operational headquarters in Strada Statale Padana Superiore 317 – 20055 – Vimodrone (Mi) Tel +39 02 265152 1; Fax +39 02 265152 21; e-mail: info@fazzini.it , quality@fazzini.eu, under their own responsibility

DECLARE

- According to the European Medical Device Directive 93/42 EEC, , ART. 1, paragraph 2 sec. a), a Medical Device is *"any instrument, apparatus, appliance, material or product, whether used alone or in combination, including the needed software for its proper application intended by the manufacturer to be used for human beings for the purpose of:*
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
  - investigation, replacement or modification of the anatomy or of a physiological process,
  - control of conception,
  and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means";
  the validity of which ceased on 05/26/2021 with the entry into force of the 2017/745 EU Regulation, which in ART. 2, paragraph 2 a **Medical Device** is:
  "any instrument, apparatus, appliance, software, implant, reagent, material or other product intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
  - *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
  - *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
  - *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*

  and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
  The following products shall also be deemed to be medical devices:
  - *devices for the control or support of conception;*
  - *products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point."*

  and what is reported in Annex XVI of the Regulations;
  THE LISTED PRODUCTS DO NOT COME WITHIN THE SCOPE OF THE DIRECTIVE 93/42 EEC AND REGULATION 2017/745 EU, FOR THIS REASON, THEY ARE NOT MEDICAL DEVICES AND THEREFORE HAVE NO CE MARKING FOR THIS PURPOSE.

- also, FAZZINI S.R.L., under its own responsibility, issues the following declaration, made pursuant to articles 46 and 47 with reference to art. 76 and in the provisions contained in art. 38 of the Presidential Decree 28 December 2000 n. 445,

CERTIFY COMPLIANCE

of the products to the provisions on safety pursuant to Legislative Decree 81/2008 and subsequent amendments.

- Finally, FAZZINI S.R.L.,

DECLARES

that the items listed below have been manufactured in compliance with the state of the art, through a scrupulous assesment of the risk in the use of the same, taking into account the restrictions on the use of chemicals contained in the raw materials of which it is composed and taking care to set it up with the most care of the production chain in order to put it on the market without defects.

What is defined and declared refers to the following products:

Baby scales
Bathroom scale
Bedside Lockers
Cabinets
Empty bags
Height rods
Lamps
Laundry baskets
Medication Trolleys
Mounting steps
Chairs
Stools
Stainless steel Instrument trolleys
Trolleys
Swaddling tables
Emergency scissors
Ward Screens
Multipurpose carts
Waste Bins
Veterinary tables and equipment
Bathroom scales
Overbed tables
Mattresses
Pillows
Bad pan
Male Urinal female urinal (Plastic)

FAZZINI SRL
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20090 VIMODRONE (MI) ITALY
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VAT IT826520156