Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. _____

Solicitantul Labromed Laborator SRL, cu sediul str. Trandafirilor, 15., Chisinau,
(adresa)
tel./fax: (022) 000 824, e-mail labromed.laborator@gmail.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:

- Tracheostoma HME, model Artificial Noses Type 302 43.009.05.706

Se anexează următoarele acte:
a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
b) certificatul de conformitate CE valabil pentru dispozitivele fabricate, după caz;
c) actul prin care producătorul își desemnează reprezentantul.

Data 17.09.2023 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 Ermicev Alexandr
Date: 2023.09.15 17:16:05 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: Labromed Laborator SRL, cu sediul str. Trandafirilor, 15, Chisinau,

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:

- Tracheostoma HME, model Artificial Noses Type 302 43.009.05.706

Sunt autentice şi corespund realităţii.

Ermicev Alexandr, Director
Numele, prenumele şi funcţia

Semnătura

Data 17.09.2023

DAHLHAUSEN®

EG-KONFORMITÄTSERKLÄRUNG gemäß Richtlinie 93/42/EWG
EC Declaration of Conformity acc. to Directive 93/42/EEC

Wir, P. J. Dahlhausen & Co. GmbH, Emil-Hoffmann-Str. 53, 50996 Köln, erklären hiermit eigenverantwortlich, dass unsere nachfolgend genannten Medizinprodukte den Anforderungen der Richtline 93/42/EWG über Medizinprodukte entsprechen:

We, P. J. Dahlhausen & Co. GmbH, Emil-Hoffmann-Str. 53, 50996 Cologne, hereby declare under our sole responsibility that the medical devices described hereafter are in conformity with the provisions of the Directive 93/42/EEC on medical devices:

Produkt: *Product:*	Künstliche Nase *Tracheostoma HME*
REF:	43.009.05.705 – 43.009.05.711
Verfahren gemäß RL 93/42/EWG: *Procedure acc. to MDD 93/42/EEC:*	Anhang II ohne (4). *Annex II excluding (4)*

Die Erklärung basiert auf dem EG-Zertifikat, das von der TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München (Benannte Stelle Nr. 0123), in Übereinstimmung mit der Richtlinie 93/42/EWG über Medizinprodukte ausgestellt wurde (Zertifikat-Nr. G1 015692 0502 Rev. 01).

The declaration is based on the EC-Certificate issued by the TÜV Süd Product Service GmbH, Ridlerstr. 65, 80339 Munich (notified body no. 0123), in accordance with the Council Directive 93/42/EEC concerning medical devices (Certificate No. G1 015692 0502 Rev. 01).

Unser Qualitätsmanagementsystem entspricht den Anforderungen der DIN EN ISO 13485:2016 und ist von einer akkreditierten Zertifizierstelle (TÜV SÜD Product Service GmbH) zertifiziert.

Our Quality Management System meets the requirements of the DIN EN ISO 13485:2016 and is certified by an accredited certification body (TÜV SÜD Product Service GmbH).

Hiermit erklären wir, dass wir für die Erstellung dieser EG-Konformitätserklärung die alleinige Verantwortung tragen.

We hereby declare that we are solely responsible for the preparation of this EC Declaration of Conformity.

Diese Erklärung ist gültig bis zum 26.05.2024. / *This declaration is valid until 26.05.2024.*

Köln / *Cologne*, 05.05.2021

P. J. Dahlhausen & Co. GmbH

P. Hardt

Petra Hardt
Leitung QM/RA
Manager QM/RA

P. J. Dahlhausen & Co. GmbH • Emil-Hoffmann-Str. 53 • 50996 Köln • Germany
Tel: +49 (0) 2236 3913-0 • Fax: +49 (0) 2236 3913-109
info@dahlhausen.de • www.dahlhausen.de

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 015692 0502 Rev. 01

Manufacturer:

P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53
50996 Köln
GERMANY

Product Category(ies): **Sterile and non-sterile medical devices including medical disposables for anaesthesia, surgery, intensive care and ward equipment (class IIa and IIb) as well as spinal needles (class III)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713163695+713175772

Valid from: 2020-07-13
Valid until: 2024-05-26

Date, 2020-07-13

Christoph Dicks
Head of Certification/Notified Body

IATROMED LABORATOR S.R.L.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

TÜV SÜD ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 015692 0502 Rev. 01

Medical Devices class IIa

Products / Product Groups:

Sterile autological blood transfusion systems
Filters
Sterile transfusion devices
Silicone respiratory tubes

Sterile scalpels and scalpel blades
Sterile redon bottles
Sterile suction tubes
Sterile suction kits
Sterile wound drainage systems
Sterile arterial embolectomy catheters

Humidifiers
Artificial noses

Sterile catheters and accessories
Sterile trocar and thoracic catheters

Oxygen therapy accessories
Accessories for respiration
Identy loops

Sterile Dermal Biospsy Punch

Faecal Management System

Medical Devices class IIb

Products / Product Groups:

Disposable electrosurgical pencils
Disposable neutral electrodes

Balloon catheter
Defibrillation electrodes

Medical Devices class III

Spinal needles

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstraße 65 · 80339 Munich · Germany

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DAHLHAUSEN®

P.J. Dahlhausen & Co. GmbH
Alles Gute fürs Kranzend aus

Emil-Hoffmann-Straße 53
50996 Köln - Germany
Tel. +49 (0) 2236 3913 - 0
Fax +49 (0) 2236 3913 - 399
info@dahlhausen.de
www.dahlhausen.de

17.03.2023

To Authorities in the Republic of Moldova,

Letter of Authorization

We,

P.J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53
50996 Cologne
Germany

declare and confirm that

Labromed Laborator SRL
fiscal code 1012600001177
with registered office at
str. Cuza Voda 30/1
Chisinau, MD 2060
Republic of Moldova

is our distributor for our products and is currently authorized to sell, attend tenders, register to local authorities mentioned products in the Republic of Moldova.
This authorization is valid for 2 (two) years from the date of issue.

Dahlhausen & Co. GmbH

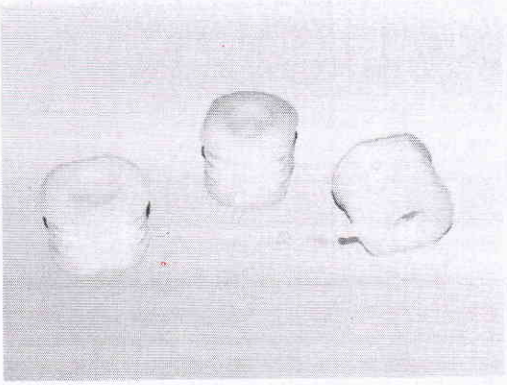
Jutta Dorenberg
Director International Sales

SOCIETATEA CU RĂSPUNDERE LIMITATĂ LABROMED LABORATOR S.R.L. REPUBLICA MOLDOVA IDNO 1012600001177

Commerzbank AG
Konto: 0 980 890 500
BLZ: 370 800 40
IBAN: DE83 3708 0040 0980 8905 00
BIC: DRESDEFF370

Deutsche Bank AG
Konto: 180 013 800
BLZ: 370 700 60
IBAN: DE07 3707 0060 0180 0138 00
BIC: DEUTDEDK

Tracheostoma



Artificial Noses Type 302

Artificial Noses Type 302, without vent, for patients with spontaneous breathing through an endotracheal or tracheostomy tube, in clinics or at home. Does not conduct electricity.

Application area:	Adult
Style:	With vent, with oxygen connection
Moisture loss (heat and moisture exchanger at Vt = 250 ml):	9 mg/l
Moisture loss (heat and moisture exchanger at Vt = 500 ml):	13,2 mg/l
Internal volume:	17 ml
Length:	29 mm
Max. tidal volume:	1.000 ml
Material:	Casing: PP; lid: TPE; foam: PE/Polyester foam (composition: polyurethane polymer) with calcium chloride coating
Sterile:	No

REF	Packing Unit	PU
43.009.05.706	50 pcs/pck	750 pcs
43.009.05.710	30 pcs/pck	720 pcs