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:

- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Numai cadru RU 4758-11
- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Balda centrala, 80x90 mm RU 4758-32
- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Lame laterale, 60x80mm RU 4758-21

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 21.09.2023 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: 2023.09.18 21:04:23 EEST
Reason: MoldSign Signature
Location: Moldova

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

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE 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 și datele furnizate pentru notificarea dispozitivului medical:

- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Numai cadru RU 4758-11
- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Balda centrala, 80x90 mm RU 4758-32
- INSTRUMENT CHIRURGICAL, model Retractor abdominal tip RICARD, Lame laterale, 60x80mm RU 4758-21

Sunt autentice și corespund realității.

Ermicev Alexandr, Director
Numele, prenumele şi funcţia

Semnătura _____

Data 21.09.2023

BECAUSE WE CARE

Konformitätserklärung / Declaration of Conformity

RUDOLF Medical GmbH + CO. KG

Zollerstrasse 1

78567 Fridingen / Germany

Wir erklären hiermit in alleiniger Verantwortung, dass unsere Medizinprodukte der Gruppe „Selbsthaltende Retraktoren" wie folgt gemäß RL 93/42 EWG, Anhang IX klassifiziert wurden

We herewith declare by our own responsibility, that our Medical Devices related to the Product Group „Self Retaining Retractors" have been classified according MDD 93/42/EEC, Annex IX,

Bezeichnung / *Description*	***Rule / Regel***	***Class / Klasse***	***UMDNS-Code / UMDNS-Nr.***
Wundhaken, selbstsperrend / *Retractors, Self-Retaining Operating*	7	IIA	13-390
Spreizer, Rippe / *Spreaders, Rib*	7	IIA	13-709

und unter Berücksichtigung folgender Richtlinie gefertigt wurden:
have been manufactured under consideration of following Council Directive:

EG-Richtlinie 93/42/EWG

European Medical Device Directive 93/42/EEC, annex IX

Die gelisteten Produkte sind konform mit den grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG und werden somit mit CE **0297** gekennzeichnet und von uns in Verkehr gebracht.

The listed products are conformal to the essential requirements of the Medical Device Directive 93/42/EEC Annex I and are therefore placed into market with CE ***0297*** *by us.*

Das Konformitätsbewertungsverfahren wurde unter Beteiligung der DQS Medizinprodukte GmbH, August-Schanz- Straße 21, 60433 Frankfurt am Main, Deutschland gemäß EG RL 93/42/EWG, Anhang II durchgeführt.

The conformity assessment has been performed under attendance by DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany according to MDD 93/42/EEC, Annex II

08.12.2020

Datum

Harald Jung
RA Manager

Diese Erklärung ist für die durch DMR-018 regulierten Produkte bis zum 20.11.2023 gültig.
This declaration is valid for the products regulated by DMR-018 until 20.11.2023.

RUDOLF Medical GmbH + Co. KG
Zollerstr. 1, 78567 Fridingen, Germany
Tel. +49 7463 9956-0, Fax +49 7463 9956-56
sales@rudolf-med.com, www.rudolf-med.com

USt. ID-Nr.: DE194017986
Amtsgericht Stuttgart HRA 450920
Steuernummer: 21083/01109

Persönlich haftender Gesellschafter: RUDOLF GmbH
Amtsgericht Stuttgart HRB 749104
Sitz der Gesellschaft: Fridingen
Geschäftsführer: Ulrich Rudolf

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Non-active intruments (MD 0106), Non-active orthopaedic implants (MD 0202), Non-active functional implants (MD 0203) and Active surgical devices (MD 1104) according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	492576 MR2
Certificate unique ID	170702227
Effective date	2018-11-21
Expiry date	2023-11-20
Frankfurt am Main	2018-11-21

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411 20 Version 1.0

Annex to certificate
Certificate registration No.: 492576 MR2
Certificate unique ID: 170702227
Effective date: 2018-11-21

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

Device family	Device	Class
	Suction / irrigation units for Minimally Invasive Surgery	IIa
	CO2 insufflators for laparoscopy and hysteroscopy	IIa
	Irrigation units for arthroscopy	IIa
	Rigid endoscopes for arthroscopy, cystoscopy, hysteroscopy, laparoscopy, nephroscopy, neuroendoscopy, otoscopy, resectoscopy, sinuscopy, thoracoscopy, ureterorenoscopy, ventriculoscopy, and microdisectomy	IIa
	Saw blades for bone surgery	IIa
	Self-retaining retractors	IIa
	Endoscope element, sheath / trocar	IIa
Implants for orthopedics and traumatology:	Drillwire, Kirschner	IIb
	Bone nails, Steinmann	IIb
HF generators and Instruments for Open and Minimally Invasive Surgery:	Electro surgical electrode holder	IIb
	Electro surgical return electrode	IIb
	Electro surgical biopsy forceps	IIb
	Electro surgical electrodes	IIb
	HF-electro surgical unit with foot switch	IIb
	Bipolar / monopolar scissors	IIb
	Bipolar / monopolar forceps	IIb
	Electro surgical suction tip	IIb
	Resectoscopes	IIb
	Endoscopic snares	IIb
	Retrieval baskets	IIb

BECAUSE WE CARE

RUDOLF Medical GmbH + Co. KG Zollerstr. 1 78567 Fridingen Germany

TO WHOM IT MAY CONCERN

Fridingen, 5th December 2022

AUTHORIZATION LETTER

We RUDOLF Medical GmbH + Co. KG, Zollerstr. 1, 78567 Fridingen, Germany, manufacturer and distributor of high-quality surgical instruments and equipment,
herewith confirm that we have authorized the company

Labromed Laborator SRL (fiscal code 1012600001177), with registered office at Str. Cuza Voda 30/1, Chisinau, MD2060, Republic of Moldova

to represent our company in the Republic of Moldova and therefore

- to represent the interests of our company before all necessary state authorities, state bodies and institutions for testing, registration and certification of products manufactured/distributed by RUDOLF Medical GmbH + Co. KG,
- to carry out the discussions relating to testing and registration of products manufactured/distributed by RUDOLF Medical GmbH + Co. KG,
- to submit all necessary documents to state authorities/bodies and institutions,
- to introduce amendments and addendum inserts to documents, after prior written approval by RUDOLF Medical GmbH + Co. KG, to give explanations, to submit additional information,
- to obtain all necessary documents for and in the name of RUDOLF Medical GmbH + Co. KG
- to receive the Registration Certificates (electronic or hard copies on paper) for and in the name of RUDOLF Medical GmbH + Co. KG.

This Letter of Authorization is valid until December 31st, 2023 and will be renewed automatically for the period of one year, if not cancelled by either RUDOLF Medical GmbH + Co. KG or Labromed Laborator SRL.

RUDOLF Medical GmbH + Co. KG

i.V. Maximilian Rudolf
Sales Director

RUDOLF Medical GmbH + Co. KG
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