

La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. _____

Solicitantul Labromed Laborator SRL, cu sediul str. Trandafirilor, 15, Chișinău,
(adresa)

tel./fax: (022) 000 824, e-mail labromed.laborator@gmail.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:

- INSTRUMENT CHIRURGICAL, model Forcep de ligatură RU 3328-18
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 6598-15
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4543-00/33
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4554-00
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4554-01

Se anexează următoarele acte:

- a) declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;
- b) certificatul de conformitate DIN EN ISO 13485:2016 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	



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: Labromed Laborator SRL, cu sediul str. Trandafirilor, 15, Chisinau,

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:

- INSTRUMENT CHIRURGICAL, model Forcep de ligatură RU 3328-18
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 6598-15
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4543-00/33
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4554-00
- INSTRUMENT CHIRURGICAL, model Rectoscop RU 4554-01

Sunt autentice și corespund realității.

Ermicev Alexandr, Director

Numele, prenumele și funcția



Semnătura

Data 21.09.2023

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 „Chirurgische Instrumente“ 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 „Surgical Instruments“ have been classified according MDD 93/42/EEC, Annex IX,

UMDNS No / UMDNS Nr.	Description	Bezeichnung	Category / Kategorie	Rule / Regel	Class / Klasse
10-174	Applicators, Clip	Applikator, Clip	09	6	I
10-226	Atomizers	Zerstäuber	09	5	I
10-500	Brushes	Bürste	09	1	I
10-519	Burs	Bohrer	04	1	I
10-718	Catheters, Eustachian	Katheter, Ohrtrumpete	09	5	I
10-762	Catheters, Urethral	Katheter, Harnröhre	09	5	I
10-824	Chisels	Meißel	09	6	I
10-829	Chisels, Orthopedic	Meißel, orthopädisch	09	6	I
10-868	Clamps, Bulldog	Klemme, Bulldog	09	6	I
10-870	Clamp, haemorrhoidal	Klemme, hämorrhoidal	09	6	I
10-902	Clips, Drape	Clip, Tuch	09	1	I
10-943	Collectors, Sputum	Sammelgefäß, Auswurf	09	1	I
11-084	Curets	Kürette	09	6	I
11-160	Dental Hand Instruments	Dental-Handinstrument	03	5	I
11-179	Dermatomes	Dermatom	09	6	I
11-263	Dilators, Tracheal	Dilatator, tracheal	09	6	I
11-266	Dilator, uterine	Dilatator, uterus	09	5	I
11-268	Dilators, Vascular	Dilatator, vaskulär	09	6	I
11-290	Dissectors	Sezierer	09	6	I
11-291	Distractors	Distraktor	09	6	I
11-504	Elevators	Elevatorium	09	6	I
11-587	Enucleators	Enukleator	09	6	I
11-701	Files	Feile	09	6	I
11-704	Filiforms	Fadeninstrument	09	9	I
11-710	Filters	Filter	05	1	I
11-726	Fittings/Adapters	Anschlüsse/Adapter	09		I
11-729	Fittings/Adapters, Luer	Anschlüsse/Adapter, Luer-Lock	09		I
11-774	Forceps	Zange	09	6	I



BECAUSE WE CARE

UMDNS No / UMDNS Nr.	Description	Bezeichnung	Category / Kategorie	Rule / Regel	Class / Klasse
11-775	Forceps, Biopsy	Zange, Biopsie	09	6	I
11-797	Forceps, Tissue	Zange, Gewebe	09	6	I
11-822	Gags	Mundsperr	09	5	I
11-835	Carriers, Medical Device	Geräteträger, Medizingerät	05	1	I
11-930	Guides, Drill	Führung, Bohrer	09	6	I
11-963	Headlights	Stirnleuchte	04	1	I
12-028	Hooks	Haken	09	6	I
12-035	Hooks, Skin	Haken, Haut	09	6	I
12-038	Hooks, Tracheal	Haken, tracheal	09	6	I
12-236	Knife Holders	Messerhalter	09	1	I
12-239	Knives	Messer	09	6	I
12-240	Knives, Amputating	Messer, Amputation	09	6	I
12-252	Knives, Scalpel	Messer, Skalpell	09	1	I
12-319	Lens Loops	Starschlinge	09	6	I
12-321	Lens Spoons	Starlöffel	09	6	I
12-340	Light Sources	Lichtquelle	09	12	I
12-374	Lingual Palatal Bars	Zungen-Gaumen-Spatel	09	5	I
12-421	Mallets	Hammer	09	1	I
12-440	Markers	Marker	09	1	I
12-547	Mirrors	Spiegel	09	1	I
12-549	Mirrors, Laryngeal	Spiegel, laryngeal	09	5	I
12-726	Needle Holders	Nadelhalter	09	6	I
12-729	Needles	Nadel	09	1	I
12-844	Osteotomes	Osteotom	09	6	I
12-986	Percussors	Perkussionshammer	09	6	I
12-989	Perforators	Perforationsinstrument	09	6	I
13-043	Pinwheels	Sensibilitätsmesser	09	1	I
13-117	Probes	Sonde	09	6	I
13-228	Punches	Stanze	09	6	I
13-230	Punches, Biopsy	Stanze, Biopsie	09	6	I
13-288	Rasps	Raspel	09	6	I
13-368	Retainers	Fixierung	09	1	I
13-373	Retractors	Wundhaken	09	6	I
13-416	Rongeurs	Hohlmeißelzange	09	6	I
13-447	Blades, Saw	Klinge, Säge	09	6	I
13-448	Saws	Säge	09	6	I
13-480	Scissors	Schere	09	6	I
13-517	Screwdrivers, Bone	Schraubendreher, Knochen	09	6	I
13-858	Supports	Stütze	09	1	I
13-630	Snares	Schlingeninstrument	09		
13-631	Snares, Polyp	SCHLINGENINSTRUMENT, Polyp	04		
13-644	Sounds, Uterine	Untersuchungssonde, Uterus	09		
13-645	Spatulas	Spatel	09		



UMDNS No / UMDNS Nr.	Description	Bezeichnung	Category / Kategorie	Rule / Regel	Class / Klasse
13-649	Spatulas, Lung	Spatel, Lunge	09	6	I
13-664	Specula, Nasal	Spekulum, Nase	09	5	I
13-707	Spreaders	Spreizer	09	6	I
13-730	Sterilization Containers	Sterilgutcontainer	05	1	I
13-750	Stethoscopes	Stethoskop	09	1	I
13-764	Stimulators, Auditory	Stimulator, Gehör	09	1	I
13-827	Strippers, Tendon	Stripper, Sehne	09	6	I
13-828	Stripper, Vein	Stripper, Vene	09	6	I
13-936	Syringes, Catheter	Spritze, Katheter	09	1	I
14-070	Tonsillectomes	Tonsillektomie-Instrument	09	6	I
14-105	Traction Units	Extensionseinheit	09	1	I
14-146	Trephines	Trephine	09	6	I
14-154	Trocars	Trokar	09	6	I
14-227	Tubes, Rectal	Tubus, rektal	09	5	I
14-238	Tubing	Schlauch	09	1	I
14-255	Tuning Forks	Stimmgabel	09	1	I
14-257	Tweezers	Pinzette	09	6	I
14-286	Bougies, Urethral	Bougie, Harnröhre	09	5	I
15-212	Clamps, Other	Klemme, sonstige	09	1	I
15-215	Dilators, Other	Dilatator, sonstige	09	6	I
15-221	Forceps, Other	Zange, sonstige	09	6	I
15-224	Guides, Other	Führung, sonstige	09	7	I
15-226	Knives, Other	Messer, sonstige	09	6	I
15-237	Probes, Other	Sonde, sonstige	09	6	I
15-249	Spatulas, Other	Spatel, sonstige	09	6	I
15-252	Sponges, Other	Tupfer, sonstige	09	1	I
15-256	Syringes, Other	Spritze, sonstige	09	1	I
15-266	Shields, X-ray, Other	Schutzschild, Röntgen, sonstige	09	1	I
15-308	Cables, Fiberoptic	Kabel, faseroptisch	09	1	I
15-561	Bowls	Schale	05	1	I
15-572	Cups	Becher	09	1	I
15-580	Extractor	Extraktor	09	6	I
15-594	Racks	Gestell	09	1	I
15-602	Specula	Spekulum	09	6	I
15-609	Trays	Tablett	09	1	I
15-652	Loupes	Lupe	09	1	I
15-670	Forceps, Bone	Zange, Knochen	09	6	I
15-671	Clamps, Rectal	Klemme, rektal	09	6	I
15-677	Elevators, Uterine	Elevatorium, Uterus	09	6	I
15-689	Applicators, other	Applikator, sonstige	09	6	I
15-741	Rasps, Bone	Raspel, Knochen	09	6	I
15-868	Needle Guides	Nadelführung	09	6	I
15-882	Clamps, Vascular	Klemme, Gefäß	09	6	I

UMDNS No / UMDNS Nr.	Description	Bezeichnung	Category / Kategorie	Rule / Regel	Class / Klasse
			10	6	I
16-028	Clips, Vascular	Clip, Gefäß	09	6	I
16-052	Clips, Ligating	Clip, unterbindend	09	6	I
16-055	Screws	Schraube	09	6	I
16-155	Obturator, Endoscopic	Verschlussinstrument, endoskopisch	09	6	I
16-268	Forceps, Biopsy, Flexible	Zange, Biopsie, flexible Endoskopie	09	6	I
16-269	Forceps, Biopsy, Rigid Endoscopic	Zange, Biopsie, starre Endoskopie	09	6	I
16-340	Cast Cutters, Electric	Gipssäge, elektrisch	04	12	I
16-429	Catheters, Cholangiography	Katheter, Cholangiographie	09	6	I
16-444	Appliers, Cerclage, Orthopedic	Applizierer, Cerclage, orthopädisch	09	1	I
16-467	Wire Bending Dies, ENT	Draht-Biegeform, HNO	09	1	I
16-501	Medical Gas Cylinders	Gasflasche, medizinisch	09	1	I
16-633	Spoons, Medicine	Löffel, Medikamente	09	1	I
16-767	Containers	Container	09	1	I
16-771	Staples	Klammer	09	6	I
16-870	Excavators	Exkavator	09	6	I
16-980	Probes, Arthroscopy	Sonde, Arthroskopie	09	5	I
17-633	Urethrotomes	Urethrotom	09	6	I
17-675	Approximators, Vessel	Approximator, Gefäß	09	6	I

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

Die gelisteten Produkte sind konform mit den grundlegenden Anforderungen des Anhang I der EG-Richtlinie 93/42/EWG und werden somit mit **CE** 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 marked with **CE** by us.

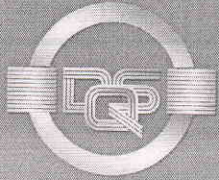
01.04.2020
 Datum

Harald Jung, RA Manager

RUDOLF
 RUDOLF Medical GmbH + Co. KG
 78635 Fridingen, Germany
 Tel. +49 7463 9956-0
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 info@rudolf-med.com
 www.rudolf-med.com

Diese Erklärung ist für die durch DMR-001 regulierten Produkte bis zum 26.05.2024 gültig.
 This declaration is valid for the products regulated by DMR-001 till 26 May 2024.





CERTIFICATE



This is to certify that the company

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;
Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems with reusable blade attachments, HF surgical equipment, non-active implants, sterilization support systems and endoscopes.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no. 492576 MP2016
Certificate unique ID 170774649
Effective date 2021-07-16
Expiry date 2024-07-15
Frankfurt am Main 2021-07-16

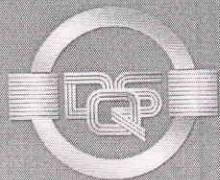
DAKKS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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

Dr. Thomas Feldmann
Head of Certification Body



Annex to certificate
Certificate registration No.: 492576 MP2016
Certificate unique ID: 170774649
Effective date: 2021-07-16

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
Germany

Location

537401
RUDOLF Medical GmbH + Co. KG
Produktion
Tuttlingerstr. 4
78567 Fridingen
Germany

537402
RUDOLF Medical GmbH + Co. KG
Verwaltung
Zollerstrasse 1
78567 Fridingen
Germany

Scope

The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;
Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems with reusable blade attachments, HF surgical equipment. non-active implants, sterilization support systems and endoscopes.

The development, manufacture, service and sale of surgical instruments, equipment and following medical devices;
Suction systems, irrigation systems, insufflators, light sources, camera systems, image storage/transmission systems, equipment trolleys, self retaining retractors, morcellator systems with reusable blade attachments, HF surgical equipment. non-active implants, sterilization support systems and endoscopes.



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

