BUREAU VERITAS
Certification

LABOMED INC.

2728 S. LA CIENEGA BLVD.
LOS ANGELES, CA 90034 USA

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

SALES, MARKET, DESIGN, MANUFACTURE, WAREHOUSE, DISTRIBUTE AND SERVICE OF SCIENTIFIC INSTRUMENTS

Original cycle start date: **August 16, 2016**

Certification / Recertification cycle start date: **August 16, 2019**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **August 15, 2022**

Certificate No. **US013491** Version: **1**

Signed on behalf BVCH SAS – UK Branch

Certification body address: ***5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom***
Local office: ***16800 Greenspoint Park Drive, Suite 300S, Houston, TX 77060***

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization. To check this certificate validity please call: ***+(800) 937-9311***

UKAS MANAGEMENT SYSTEMS
0008

BUREAU VERITAS

EC Declaration of Conformity

In accordance with EN ISO 17050-1:2010

We

Labomed, Inc.

at 2728 S. La Cienega Blvd., Los Angeles, CA 90034 U.S.A.

in accordance with the following Directive(s):

93/42/EEC	The Medical Devices Directive
73/23/EEC	Low Voltage Directive (as amended 93/68/EEC)
89/336/EEC	EMC Directive (as amended 93/68/EEC)

hereby declare under our sole responsibility that:

Equipment:	FACA-200	FACA-200-ISE	BAS-150 TS PLUS	H-7028
	FACA-261	FACA-261-ISE	BAS-120 TS	IO-005
	FACA-301	FACA-301-ISE	BAS-100 TS	SCO-2000
	FACA-401	FACA-401-ISE	EMR-500	SCO-2002
	FACA-601	FACA-601-ISE	EMW-600	SCO-2004
	FACA-801	FACA-801-ISE	H-7021/H-7022	VH-22

Standard is in conformity with the applicable requirements of the Declared Standard(s):

Conformity is Declared as:

IEC 1010-1; EN 55011 Group 1 Class A;

EN 50082-1: 1992: IEC 801-2:1991

IEC 801-3:1984; IEC 801-4:1988;

UL 3101-1 (1993) & CAN/CSA C22.2 No. 1010.1-92

ETL Mark for Safety

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directive.

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directive.

Signature

Date: January 1 – 2016

Expiration Date: Expiration Date: January 1, 2022

CE

ORIGINAL

DECLARATION OF CONFORMITY

CE

Application of Council Directive(s):	73/23/EEC - Low Voltage Directive 89/336/EEC - EMC Directive (both as amended by 93/68/EEC)
Standard(s) to which Conformity is Declared:	IEC 1010-1; EN 55011 Group 1 Class A: EN 50082-1: 1992: IEC 801-2:1991 IEC 801-3:1984; IEC 801-4:1988; UL 3101-1 (1993) & CAN/CSA C22.2 No. 1010.1-92 ETL Mark for Safety
Manufacturer's Name:	LABOMED, INC.
Manufacturer's Address:	2728 S. La Cienega Blvd.-Los Angeles-CA-90034-U.S.A.
Importer's Name:	_____
Item Model No.:	_____
Item Model No.:	_____
Item Model No.:	_____
Type of Equipment:	SCIENTIFIC INSTRUMENTS: ANALYTICAL AND DIAGNOSTIC
Model Number and Name:	1 - UV-VIS AND VISIBLE SPECTROPHOTOMETERS 2 - MEDICAL DIAGNOSTIC PRODUCTS 3 - MICROSCOPES 4 - MICROSCOPE CAMERAS 5 - HPLC 6 - ATOMIC ABSORPTION SPECTROPHOTOMETER

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s) and is thus eligible to bear the CE Mark.

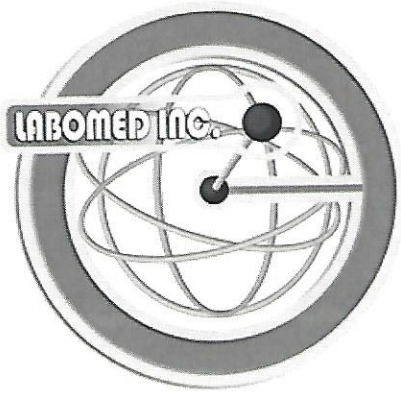
Signature

Date: January 1, 2021
Expiration Date: January 1, 2025

CE

United States of America

United States Patent and Trademark Office



Reg. No. 5,056,986

Registered Oct. 11, 2016

Int. Cl.: 9

Trademark

Principal Register

Labomed, Inc. (CALIFORNIA CORPORATION)
2921 S. La Cienega Blvd, Suite A
Culver City, CA 90232

CLASS 9: scientific apparatus and instruments, namely, spectrophotometers and accessories therefor, namely, peltier system, reflection system, integrating sphere, adjustable angle solid sample holder; biochemistry analyzers for laboratory use; digital cameras; flow-through peristaltic pumps; thermoelectric controllers; and cuvettes; except for microscopes and microscopy-related products in the life sciences and medical fields

FIRST USE 2-28-1998; IN COMMERCE 2-28-1998

The mark consists of an outer circle with concentric inner circle having series of smaller circles defining orbit design within inner circle, with a first small solid circle at center having first line extending rightwardly to the inner circle and a second line extending upwardly to a second small solid circle, with "LABOMED INC." superimposed at left of second solid circle with a line framing the text and the second solid circle.

No claim is made to the exclusive right to use the following apart from the mark as shown: "INC."

SER. NO. 85-714,978, FILED 08-28-2012
KEVON CHISOLM, EXAMINING ATTORNEY

Michelle K. Lee

Director of the United States
Patent and Trademark Office

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 213-10-2019

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from October 08, 2019 to October 07, 2021.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 213-10-2019
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 213-10-2019

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

Name of Product(s)

Clinical Chemistry Analyzer
BAS-100TS
BAS-120TS
BAS-150TS
CB-200
DW-20
EMR-500
EMW-600
FACA-200
FACA-200/ISE
FACA-261
FACA-261/ISE
FACA-301
FACA-301/ISE
FACA-401
FACA-401/ISE
FACA-601
FACA-601/ISE
FACA-801
FACA-801/ISE
H-7021
H-7028
IO-005
SCO-2000
SCO-2002
SCO-2004
VH-22

----------END OF PRODUCT LIST----------

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7173-3-2021

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

LB Microscopes

Name of Manufacturer/Distributor, Address

Name of Manufacturer
LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 17, 2021 to March 16, 2023.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7182-3-2021

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Two Pages)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 17, 2021 to March 16, 2023.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7182-3-2021
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7182-3-2021

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

Name of Product(s)

ALT/GPT Alanine Aminotransferase
AST/GOT Aspartate Aminotransferase
y-GT/GGT y-Glutamyltransferase
ALP/AKP Alkaline Phosphatase
TBILI Total Bilirubin*
TBILI Total Bilirubin*
DBILI Direct Bilirubin*
DBILI Direct Bilirubin*
TP Total Protein*
ALB Albumin*
CHE Cholinesterase
TBA Total Bile Acid*
UREA Urea*
CREA Creatinine*
UA Uric Acid*
CHOL Cholesterol*
TG Triglycerides*
HDL-C High Density Lipoprotein Cholesterol
LDL-C Low Density Lipoprotein Cholesterol
APOA1 Apolipoprotein A 1*
APOB Apolipoprotein B*
CK Creatine Kinase
CK-MB Creatine Kinase MB Isoenzyme
LOH Lactate Dehydrogenase
a-HBDH a-Hydroxybutyrate Dehydrogenase
a-AMY a-Amylase
LAP Leucine Aminopeptidase
Ca Calcium*
Cl Chloride*
p Inorganic Phosphorus*
Mg Magnesium*
Fe Iron*
GLU Glucose*
GLU Glucose*
FMN Fructosamine*
HBA1C Hemoglobin HBA1C
IgA Immunoglobulin A*
IgA Immunoglobulin A*
IgG Immunoglobulin G*
IgG Immunoglobulin G*
IgM Immunoglobulin M*
IgM Immunoglobulin M*
C3 Complement Component 3*
C3 Complement Component 3*
C4 Complement Component 4*
C4 Complement Component 4*
PA Prealbumin•

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7182-3-2021

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

PA Prealbumin•
LA Lactic Acid*
CRP CRP (C-reactive protein)
HBA1C Hemoglobin HBA1C
CAL Multi-Parameter Biochemistry Calibrator
CON Multi-Parameter Biochemistry Control
NCH Highly-effective Detergent (NCH Detergent)
NCH Highly-effective Detergent (NCH Detergent)
PT Prothrombin Time
APTT Activate PartialThromboplastin Time
TT ThrombIn Time
FIB Fibrinogen
Standard Solution A
Standard Solution B
Electrode Reconditioning Solution
Electrode Deproteinization Solution
Electrode Electrolytic Solution
Reference Electrode Solution
Diluent (HA-3D)
Deprotein (HA-3D)
Hemolysin (HA-3D)
Detergent (HA-3D)
----------END OF PRODUCT LIST----------

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7178-3-2021

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 17, 2021 to March 16, 2023.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7178-3-2021
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

----END OF MANUFACTURER/DISTRIBUTOR LIST----

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 7178-3-2021

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

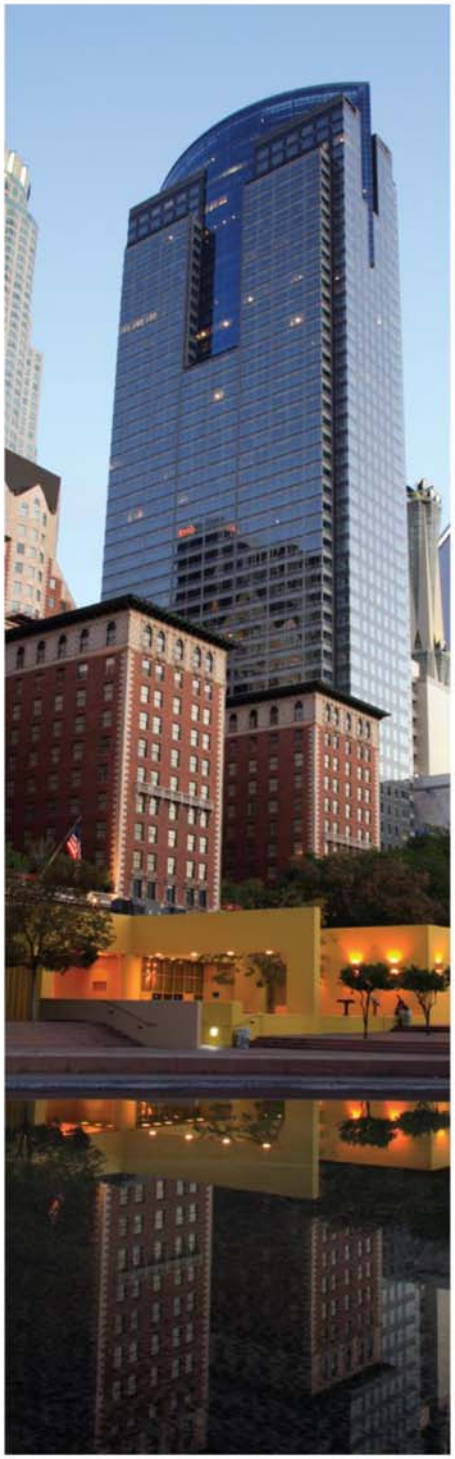
LABOMED, INC.
2728 SOUTH LA CIENEGA BLVD.
Los Angeles, CA USA 90034

Name of Manufacturer

LABOMED, INC.
2728 S LA CIENEGA BLVD
LOS ANGELES, CA USA 90034

Name of Product(s)

Spectrophotometer 2000RS
Spectrophotometer 2000RSP
Spectrophotometer 23
Spectrophotometer 23RS
Spectrophotometer 24RS
Spectrophotometer AAS-3700
Spectrophotometer AAS-3800
Spectrophotometer AAS-3900
Spectrophotometer AAS-4000
Spectrophotometer AAS-4100
Spectrophotometer UV-2502
Spectrophotometer UV-2505
Spectrophotometer UV-2510TS
Spectrophotometer UV-2550
Spectrophotometer UV-2650
Spectrophotometer UVD-2950
Spectrophotometer UVD-2960
Spectrophotometer UVD-3000
Spectrophotometer UVD-3200
Spectrophotometer UVD-3500
Spectrophotometer UVS-2700
Spectrophotometer UVS-2800
Spectrophotometer W-2100
----------END OF PRODUCT LIST----------



LOS ANGELES AREA
CHAMBER OF COMMERCE

2015

LOS ANGELES AREA CHAMBER OF COMMERCE

PROUD MEMBER

Labomed, Inc.

Member Number: 94155

BOLD IN **BUSINESS**

Republic of Iraq
Ministry of Health

TECHNICAL AFFAIRS
DIRECTORATE
Registration department

No. / 290 /د.ا.ف/٣/٣/٩
Date / 2-9-2009

MEDICAL APPLIANCES COMPANY REGISTRATION CERTIFICATE

TO : **LABOMED INC / USA**

DEAR SIR :

THIS IS TO NOTIFY YOU THAT REGISTRATION COMMITTEE HAS DECIDED TO REGISTER (**YOUR COMPANY**) UNDER DECISION NO. (**588**) AT SESSION NO. (**144**) DATED (**6 / 8 / 2009**)

BEST REGARDS

D. EMAN ASIM .M.AMIN
GENERAL DIRECTOR
31 / 8 / 2009

ZAINAB G. JABUR
REG. DEPT. MANAGER
30/ 8 / 2009

وزارة الصحة العراقية
M.O.H.
قسم التسجيل
Reg
دائرة الامور الفنية

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
قطاع الأجهزة والمنتجات الطبية

Executive Department of Registration and Licensing

الإدارة التنفيذية للتسجيل والتراخيص

رخصة ممثل قانوني

Authorised Representative License

An **Authorised Representative License** has been issued to

أصدرت رخصة ممثل قانوني لـ

Bassam Trading Co.,Ltd

Establishment National Registry Number

MDNR09100295

Issuing Authority -	Saudi Food and Drug Authority	**جهة الإصدار -** الهيئة العامة للغذاء والدواء
Enabling Legislation -	Medical Device Interim Regulation supported by Implementing Rule MDS-IR5 on Licensing of Authorised Representatives	**المرجع القانوني -** لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية MDS-IR 5 الخاصة بترخيص الممثل القانوني
Licensed Activity -	acting on behalf of the MANUFACTURER for the medical device within the KSA according to the AR agreement with the exception to the paragraph pertaining additional tasks and Provisions	**نشاط المنشأة -** التمثيل القانوني للمصنع داخل المملكة العربية السعودية وفقاً لاتفاقية التمثيل القانوني فيما عدا المادة الخاصة بالمهام والأحكام الإضافية الاختيارية.
Manufacturer:	**Labomed Inc.**	**المصنّع:**
Device Category(ies):	Laboratory Equipment, Ophthalmic and Optical Devices, Reusable Devices,	**أصناف الأجهزة والمنتجات الطبية:**
License Number :	**081900123**	**081900123** رقم الرخصة :
Issuing Date (dd/mm/yyyy) :	**03/09/2019**	**1441/01/04** تاريخ الإصدار :
Expiry Date (dd/mm/yyyy) :	**22/08/2020**	**1442/01/03** تاريخ الانتهاء :

Executive Director of Registration & Licensing

المدير التنفيذي للتسجيل و التراخيص

تم ختم هذه الرخصة الكترونياً ولا تعتبر هذه الرخصة صحيحة إلا بعد التحقق من صحة البيانات الواردة فيها من قبل الجهة المستفيدة وذلك من خلال الدخول على الرابط التالي
https://mdel.sfda.gov.sa/PublicModule/LicensedApplicants.aspx:

Executive Department of Registration and Licensing

الإدارة التنفيذية للتسجيل والتراخيص

قائمة مرفقة برخصة ممثل قانوني

Annex of Authorised Representative License

Issuing Date:	03/09/2019	**Annex Number:**	081900123	رقم المرفق:	1441/01/04 :تاريخ الإصدار
Expiry Date:	22/08/2020	**Number of Annex Pages:**	1	عدد صفحات المرفق:	1442/01/03 :تاريخ الإنتهاء

This annex is an integral part of the **Authorised Representative License** number **081900123** which has been issued to:

يعد هذا المرفق جزءاً مكملاً لرخصة الممثل القانوني رقم **081900123**
والمصدَّرة لـ :

Establishment National Registry Number

MDNR09100295

	Manufacturer's Name	Country	Device Category (ies)
1.	Labomed Inc.	USA	Ophthalmic and Optical Devices
2.	Labomed Inc.	USA	Reusable Devices
3.	Labomed Inc.	USA	Laboratory Equipment