Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
BENCH TOP LABORATORY CENTRIFUGE	LABY	T-4M T-8M SP-8M T-8BL SP-8BL T-9BL T-20BL T-24BL	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,
For and on behalf of M/s. LABY INSTRUMENTS INDUSTRY

For Laby Instruments Industry

Authorized Signatory

Sole Prop.

Encl:

777E- Final notifi 4 exempt of non steril cat A MDR
CLASS A - CUSTOM EXEPMTION

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— BENCH TOP LABORATORY CENTRIFUGE	LABY	Family	General Hospital	Class A			No	

Grouping Description: FAMILY
Intended Use: equipment utilized in laboratories to separate and purify molecular mixtures in a liquid medium based on their density gradient.
Product Description: equipment utilized in laboratories to separate and purify molecular mixtures in a liquid medium based on their density gradient.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE, AS PER CUSTOMER REQUIREMENT
Accessory/Components:
Model Detail: T-4M T-8M SP-8M T-8BL SP-8BL T-9BL T-20BL T-24BL:equipment utilized in laboratories to separate and purify molecular mixtures in a liquid medium based on their density gradient. ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
REFRIGERATED CENTRIFUGE MACHINE	LABY	SP-50 SP-60 SP-70BL SP-80BL T-50 T-60 T-70BL	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s. Laby Instruments Industri,

For Laby Instruments Industri,

Sole Prop.

Authorized Signatory

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

Manufacturers:
Lab Equipments: Centrifuges, Refrigerated Centrifuges, pH meters, H.B. Meter, Colorimeter Electrophoresis and Power Supplies, Magnetic Stirrers, Anarobic Jar, Vortex Mixture etc.

SSI Reg. No.: 060021100297 GSTIN : 06ACTPS5454M2ZO

E-mail : laby63@gmail.com Website: www.labyindia.com

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— REFRIGERATED CENTRIFUGE MACHINE	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: for the separation of microliter temperature-sensitive heterogeneous mixtures or samples.
Product Description: for the separation of microliter temperature-sensitive heterogeneous mixtures or samples.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE, AS PER CUSTOMER REQUIREMENT
Accessory/Components:
Model Detail: SP-50 SP-60 SP-70BL SP-80BL T-50 T-60 T-70BL:for the separation of microliter temperature-sensitive heterogeneous mixtures or samples.
,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
GEL DOCUMENTATION SYSTEM	LABY	GD-1 GD-2	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s.Laby Instruments Industry

Authorized Signatory

For Laby Instruments Industry
Sole Prop.

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— GEL DOCUMENTATION SYSTEM	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: used in molecular biology laboratories for the imaging and documentation of nucleic acid and protein suspended within polyacrylamide or agarose gels.
Product Description: used in molecular biology laboratories for the imaging and documentation of nucleic acid and protein suspended within polyacrylamide or agarose gels.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: GD-1 GD-2:used in molecular biology laboratories for the imaging and documentation of nucleic acid and protein suspended within polyacrylamide or agarose gels. ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
GEL AND PAPER ELECTROPHORESIS HORIZONTAL AND VERTICAL	LABY	GE-1 GE-2 DVG-2 PEV-2 PEH-1	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s. Laby Instruments Industry

For Laby Instruments Industry

Sole Prop.

Authorized Signatory

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

Manufacturers:
Lab Equipments: Centrifuges, Refrigerated Centrifuges, pH meters, H.B. Meter, Colorimeter Electrophoresis and Power Supplies, Magnetic Stirrers, Anarobic Jar, Vortex Mixture etc.

SSI Reg. No.: 060021100297 GSTIN : 06ACTPS5454M2ZO

E-mail : laby63@gmail.com Website: www.labyindia.com

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— GEL AND PAPER ELECTROPHORESIS HORIZONTAL AND VERTICAL	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: In horizontal gel electrophoresis, the gel matrix is cast horizontally and submerged in a continuous running buffer while in vertical gel electrophoresis, the gel is vertically oriented and the buffer system is discontinuous.
Product Description: In horizontal gel electrophoresis, the gel matrix is cast horizontally and submerged in a continuous running buffer while in vertical gel electrophoresis, the gel is vertically oriented and the buffer system is discontinuous.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: GE-1 GE-2 DVG-2 PEV-2 PEH-1:In horizontal gel electrophoresis ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
ELECTRIC SYRINGE AND NEEDLE DESTROYER	LABY	ND-100 ND-120	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s. Laby Instruments Industry

Authorized Signatory

For Laby Instruments Industry

Sole Prop.

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— ELECTRIC SYRINGE AND NEEDLE DESTROYER	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: prevents healthcare personnel from coming in contact with the needle while disposing
Product Description: prevents healthcare personnel from coming in contact with the needle while disposing
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: ND-100 ND-120:prevents healthcare personnel from coming in contact with the needle while disposing ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
CYTO CENTRIFUGE	LABY	CYTY-8	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s. Laby Instruments Industry

Authorized Signatory

For Laby Instruments

Sole Prop.

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

Manufacturers:
Lab Equipments: Centrifuges, Refrigerated Centrifuges, pH meters, H.B. Meter, Colorimeter Electrophoresis and Power Supplies, Magnetic Stirrers, Anarobic Jar, Vortex Mixture etc.

SSI Reg. No.: 060021100297 GSTIN : 06ACTPS5454M2ZO

E-mail : laby63@gmail.com Website: www.labyindia.com

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— CYTO CENTRIFUGE	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: to concentrate cells in fluid specimens onto a microscope slide so that they can be stained and examined.
Product Description: to concentrate cells in fluid specimens onto a microscope slide so that they can be stained and examined.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: CYTY-8:to concentrate cells in fluid specimens onto a microscope slide so that they can be stained and examined. ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
U.V. TRANSILLUMINATORS	LABY	TI-20 T-21 TI-22 TI-23 TI-24 TI-25 TI-50 TI-60	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s. Laby Instruments Industry

For LABY INSTRUMENTS INDUSTRY

Authorized Signatory

SOLE PROP.

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— U.V. TRANSILLUMINATORS	LABY	Family	General Hospital	Class A	NIL		No	

Grouping Description: FAMILY
Intended Use: use ultraviolet radiation (UVR) to visualize proteins, DNA, RNA, and their precursors in a gel electrophoresis procedure.
Product Description: use ultraviolet radiation (UVR) to visualize proteins, DNA, RNA, and their precursors in a gel electrophoresis procedure.
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: TI-20 T-21 TI-22 TI-23 TI-24 TI-25 TI-50 TI-60:use ultraviolet radiation (UVR) to visualize proteins ,
Drug Detail: -NA-

Laby™

Laby Instruments Industry

Works : 62, Industrial Estate, Ambala Cantt - 133 006
Haryana INDIA, Mb. : 9992929115
An ISO : 9001, ISO : 13485 GMP CE

TO WHOM SO EVER IT MAY CONCERN

Declaration of Conformity –Class A (Non-sterile & Non-Measuring)

Generic Name	Brand Name	Model Detail	Device Class	File no
BLOOD BAG TUBE SEALER	LABY	BBS-10 BBS-11	Class A	LABYI-Ambal-HR/M/MD/014413

With reference to the subject, we hereby declare that the product mentioned in the above table is in Class A (Non-Sterile and Non-Measuring) as per the schedule 1, rule 4 of Medical Device Rules 2017.

As per notification Ministry of Health and Family Welfare Gazette notification no. G.S.R. 777E dated 14th October 2022 (Notification attached as an annexure to this declaration), these rules called as Medical Device Sixth Amendment Rules, 2022, under these rules Class A Medical Devices (Non- sterile and Non-measuring) classified as Class A medical Device as per First Schedule are required to be registered through CDSCO online portal whereby only a registration number is generated.

No separate certificate will be issued for Class A Medical Devices (Non- sterile and Non- measuring) classified as Class A medical Device as per First Schedule.

However Registration of the devices are to be made on the identified WWW.CDSCOMDONLINE.GOV.IN portal and the registration number generated will be considered as the product registration as per above said rules- G.S.R. 777E.

We, also declare that all our products are complying with the ISO 13485:2016 and IMDR, 2017 requirements for the safety and efficacy of the products.

Yours faithfully,

For and on behalf of M/s.Laby Instrments Industry

For Laby Instruments Industry

Sole Prop.

Authorized Signatory

Encl:

- 777E- Final notifi 4 exempt of non steril cat A MDR
- CLASS A - CUSTOM EXEPMTION

LABYI-Ambal-HR/M/MD/014413

Device Details

Search:

	S.No.	Generic Name	Brand Name	Notified Grouping Category	Notified Category	Device Class	Shelf Life	Sterlization	Contains Drug	Edit
☐	1	— BLOOD BAG TUBE SEALER	LABY	Family	General Hospital	Class A	NIL	Non-Sterilized	No	

Grouping Description: FAMILY
Intended Use: seals the tube of blood bag without causing haemolysis and leakage of blood
Product Description: seals the tube of blood bag without causing haemolysis and leakage of blood
Material of Construction: ALUMINIUM, STAINLESS STEEL, PLASTIC, MILD STEEL
Dimension: NA
Storage Condition: ROOM TEMPRATURE
Pack size: SINGLE
Accessory/Components:
Model Detail: BBS-10 BBS-11:seals the tube of blood bag without causing haemolysis and leakage of blood ,
Drug Detail: -NA-

E-MAIL/SPEED POST

भारत सरकार GOVERNMENT OF INDIA
वित्त मंत्रालय MINISTRY OF FINANCE
राजस्व विभाग DEPARTMENT OF REVENUE
केन्द्रीय अप्रत्यक्ष कर एवं सीमाशुल्क बोर्ड
CENTRAL BOARD OF INDIRECT TAXES AND CUSTOMS
सीमा शुल्क संयुक्त आयुक्त का कार्यालय
OFFICE OF THE JOINT COMMISSIONER OF CUSTOMS
कोचीन अन्तर्राष्ट्रीय हवाई अड्डा, नेडुम्बाश्शेरि -683111
COCHIN INTERNATIONAL AIRPORT, NEDUMBASSERY
Website: www.cochincustoms.gov.in
E-mail: cochincustoms@nic.in
Control Room: 0484-2610077
Fax: 0484-2610075

Azadi Ka Amrit Mahotsav

CIRCULAR

Sub: Mandatory Registration and licensing of medical devices-Reg.

****

From 1st October 2022, Registration is mandatory for Class A, B, C, D of medical devices

- From 1st October Class A and B medical devices will require license. However, Class A non-measuring and non-sterile are exempted from licensing.
- All notified devices under Class C and D of medical devices will require license (List of notified products in GSR 102(E) dated 11.02.2020)
- Component & Spare Parts of Medical Devices also Need Registration

Vijesh Kumar T.G
Deputy Commissioner of Customs (ACC)

File No. S25/123/2019-20 ACC Cus
Dated: 30.09.2022

Issued to:

1. **All Custom Agents**
2. **Appraisers/Superintendents/Preventive Officers of Air Cargo**

CDSCO PRODUCT REGISTRATION NUMBER CLASS A DEVICE

S.No	File No	Devices (Brand Name)
1	LABYI-Ambal-HR/M/MD/014413	BENCH TOP LABORATORY CENTRIFUGE(LABY)
2	LABYI-Ambal-HR/M/MD/014413	REFRIGERATED CENTRIFUGE MACHINE(LABY)
3	LABYI-Ambal-HR/M/MD/014413	CYTO CENTRIFUGE(LABY)
4	LABYI-Ambal-HR/M/MD/014413	BLOOD BAG TUBE SEALER(LABY)
5	LABYI-Ambal-HR/M/MD/014413	GEL AND PAPER ELECTROPHORESIS HORIZONTAL AND VERTICAL(LABY)
6	LABYI-Ambal-HR/M/MD/014413	U.V. TRANSILLUMINATORS (LABY)
7	LABYI-Ambal-HR/M/MD/014413	GEL DOCUMENTATION SYSTEM(LABY)
8	LABYI-Ambal-HR/M/MD/014413	ELECTRIC SYRINGE AND NEEDLE DESTROYER(LABY)

रजिस्ट्री सं. डी.एल.- 33004/99 REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-15102022-239681
CG-DL-E-15102022-239681

असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 691] नई दिल्ली, शुक्रवार, अक्तूबर 14, 2022/आश्विन 22, 1944
No. 691] NEW DELHI, FRIDAY, OCTOBER 14, 2022/ASVINA 22, 1944

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 14 अक्तूबर, 2022

सा.का.नि. 777(अ).—चिकित्सा युक्ति नियम, 2017 का और संशोधन करने के लिए कतिपय नियमों का प्रारूप, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 की उपधारा (1) और धारा 33 की उपधारा (1) के अधीन यथा अपेक्षित, भारत सरकार के स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य और परिवार कल्याण विभाग) की अधिसूचना सं. सा.का.नि. 710(अ), तारीख 20 सितंबर, 2022 द्वारा भारत के राजपत्र, असाधारण, भाग II, खंड 3, उपखंड (i) में प्रकाशित किया गया था, जिसमें उन सभी व्यक्तियों से, जिनके उससे प्रभावित होने की संभावना है, उस तारीख से, जिसको उक्त अधिसूचना वाली राजपत्र की प्रतियां जनता को उपलब्ध करा दी गई थी, सात दिनों की अवधि के समाप्ति से पहले आक्षेप और सुझाव आंमत्रित किए गए थे;

और, उक्त राजपत्र की प्रतियां 20 सितंबर, 2022 को जनता को उपलब्ध करा दी गई थी;

और केन्द्रीय सरकार द्वारा उक्त नियमों पर जनता से प्राप्त आक्षेप और सुझावों पर विचार कर लिया गया है;

अत: अब, केन्द्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, और औषधि तकनीकी सलाहकार बोर्ड के साथ पूर्व कार्योत्तर परामर्श और उक्त धाराओं के प्रावधानों के अनुसार बोर्ड के सुझावों पर विचार के अधीन, चिकित्सा युक्ति नियम, 2017 का और संशोधन करने के लिए निम्नलिखित नियम बनाती है, अर्थात्:—

1. (1) इन नियमों का संक्षिप्त नाम चिकित्सा युक्ति (छठा संशोधन) नियम, 2022 है।

(2) ये राजपत्र में उनके प्रकाशन की तारीख को प्रवृत होंगे।

2. चिकित्सा युक्ति नियम, 2017 (जिसे इसमें इसके पश्चात् उक्त नियम कहा गया है) के नियम 13 में,—

(क) उपनियम (2) में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंत:स्थापित किए जाएँगे;

(ख) उपनियम (3) में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंत:स्थापित किए जाएँगे ।

3. उक्त नियमों में, नियम 14 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंत:स्थापित किए जाएँगे ।

4. उक्त नियमों में, नियम 19 च के पश्चात्, निम्नलिखित अंत:स्थापित किए जाएँगे, अर्थात्:—

"अध्याय III ख

श्रेणी क (गैर-स्टेराइल और गैर-मापन वाले) चिकित्सा युक्तियों का रजिस्ट्रीकरण

19 छ. इस अध्याय का अनुप्रयोग.— (1) यह अध्याय, उक्त नियमों की पहली अनुसूची के अनुसार, श्रेणी क चिकित्सा युक्तियों के रूप में वर्गीकृत सभी गैर-स्टेराइल और गैर-मापन वाले युक्तियों पर लागू होगा (यहां से इस अध्याय में गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति के रूप में संदर्भित किया गया है)।

(2) उपनियम (1) में निर्दिष्ट चिकित्सा युक्तियों को इस प्रयोजन के लिए स्थापित एक निर्धारित ऑनलाइन पोर्टल के माध्यम से रजिस्ट्रीकृत किया जाएगा।

19 ज. रजिस्ट्रीकरण के लिए जानकारी अपलोड करना.— (1) किसी गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्तियों का विनिर्माता चिकित्सा युक्तियों के लिए ऑनलाइन प्रणाली पर रजिस्ट्रीकरण के लिए उस चिकित्सा युक्ति से संबंधित उपनियम (2) में विनिर्दिष्ट जानकारी अपलोड करेगा।

(2) विनिर्माता चिकित्सा युक्तियों के लिए ऑनलाइन प्रणाली में निम्नलिखित अपलोड करेगा, अर्थात्:—

(i) विनिर्माण स्थल का नाम और पता;

(ii) गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्तियों का प्रदान किए जाने वाले ब्योरे:

जेनेरिक नाम	ब्रांड का नाम(यदि व्यापार चिह्न अधिनियम, 1999 के अधीन रजिस्ट्रीकृत है)	मॉडल संख्या (यदि कोई हो)	आशयित उपयोग	निर्माण की सामग्री	आयाम (यदि लागू हो)	निधानी आयु (यदि लागू हो)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) विनिर्माता यह बताते हुए वचनबंध देगा कि प्रस्तावित युक्ति, प्रथम अनुसूची के अनुसार, गैर- स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति है;

(iv) विनिर्माता स्व-प्रमाणित करेगा कि यह उत्पाद ऐसे युक्तियों की सुरक्षा और निष्पादन के अनिवार्य सिद्धांतों की जांचसूची के अनुरूप है;

(v) विनिर्माता इन नियमों में विनिर्दिष्ट मानकों के अनुपालन को स्व-प्रमाणित करेगा; और

(vi) विनिर्माता द्वारा विधिवत् हस्ताक्षरित इस उल्लेख का वचनबंध कि आवेदक द्वारा दी गई जानकारी सत्य और प्रामाणिक है।

19झ. रजिस्ट्रीकरण संख्यांक.— इस प्रयोजन के लिए स्थापित ऑनलाइन चिकित्सा युक्ति प्रणाली पर नियम 19ज के अनुसार सूचना दिए जाने के पश्चात्, गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति के लिए रजिस्ट्रीकरण संख्या सृजित हो जाएगी।

19 ञ. गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति का आयात.— (1) कोई भी व्यक्ति जो किसी गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति को आयात करना चाहता है, वह चिकित्सा युक्तियों की ऑनलाइन प्रणाली पर रजिस्ट्रीकरण के लिए उस चिकित्सा युक्ति से संबंधित उपनियम (2) में जानकारी अपलोड करेगा।

(2) आयातक चिकित्सा युक्तियों के लिए ऑनलाइन प्रणाली में निम्नलिखित अपलोड करेगा, अर्थात्:—

(i) आयातक का नाम और पता तथा विनिर्माण स्थल का नाम और पता;

(ii) गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्तियों का प्रदान किए जाने वाले ब्योरे:

जेनेरिक नाम	ब्रांड का नाम (यदि व्यापार चिन्ह अधिनियम, 1999 के अधीन रजिस्ट्रीकृत है)	मॉडल संख्या (यदि कोई हो)	आशयित उपयोग	निर्माण की सामग्री	आयाम (यदि लागू हो)	निधानी आयु (यदि लागू हो)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) आयातक यह उल्लेख करते हुए एक वचनबंध देगा कि प्रस्तावित युक्ति, प्रथम अनुसूची के अनुसार गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति है;

(iv) आयातक स्व-प्रमाणित करेगा कि उत्पाद ऐसे युक्तियों की सुरक्षा और निष्पादन के अनिवार्य सिद्धांतों की जांचसूची के अनुरूप है;

(v) आयातक इन नियमों में विनिर्दिष्ट मानकों के अनुपालन को स्व-प्रमाणित करेगा;

(vi) सक्षम प्राधिकारी द्वारा जारी किए गए मूल देश में विदेशी विनिर्माण स्थल या प्रतिष्ठान या संयंत्र रजिस्ट्रीकरण, जिस नाम से भी कहा जाए, की स्व-सत्यापित प्रति या राष्ट्रीय विनियामक प्राधिकरण द्वारा जारी नि:शुल्क बिक्री प्रमाण पत्र; और

(vii) आयातक द्वारा विधिवत् हस्ताक्षरित इस उल्लेख का वचनबंध कि आवेदक द्वारा दी गई जानकारी सत्य और प्रामाणिक है। ।

19 ट. आयात के लिए रजिस्ट्रीकरण संख्यांक.— इस प्रयोजन के लिए स्थापित चिकित्सा युक्तियों की ऑनलाइन प्रणाली पर नियम 19 ञ के अनुसार सूचना प्रस्तुत करने के बाद, गैर-स्टेराइल और गैर-मापन वाले श्रेणी क चिकित्सा युक्ति के लिए रजिस्ट्रीकरण संख्या सृजित हो जाएगी।

19 ठ. अभिलेखों का रखरखाव.— (1) विनिर्माता या आयातक, जैसी भी स्थिति हो, अपनी बिक्री या वितरण के साथ विनिर्माण या आयात से संबंधित रिकॉर्ड रखेगा।

(2) विनिर्माता या आयातक, जो भी मामलो हो, अनुज्ञापन प्राधिकारियों के अनुरोध पर रिकॉर्ड, लेबल, उपयोग के अनुदेश प्रस्तुत करेंगे।

(3) अनुज्ञापन प्राधिकारी किसी भी समय उपनियम (2) में विनिर्दिष्ट रिकोर्डों और दस्तावेजों को सत्यापित कर सकते हैं और गुणवत्ता या सुरक्षा संबंधी असफलताओं या शिकायतों की जांच कर सकते हैं।

19 ड. रजिस्ट्रीकरण का निलंबन या निरसन.— (1) राज्य अनुज्ञापन प्राधिकरण या केंद्रीय अनुज्ञापन प्राधिकरण, जैसी भी स्थिति हो, यदि उसकी राय में रजिस्ट्रीकृत व्यक्ति पूर्ण रूप से या किसी भी चिकित्सा युक्ति के संबंध में इस अध्याय के नियमों के किसी प्रावधान का पालन नहीं कर पाया है, तो रजिस्ट्रीकृत किए गए व्यक्ति को इस अशय का कारण बताओ नोटिस का उत्तर देने का अवसर प्रदान करने के बाद, कि क्यों न इस प्रकार का आदेश पारित कर दिया

जाए, लिखित में कारण बताते हुए आदेश द्वारा नियम 19- ञ या नियम 19 ठ के उपबंधों के अधीन सृजित रजिस्ट्रीकरण संख्या रद्द करने या उस अवधि के लिए जिसे वह उचित समझे, निलंबित कर सकता है।

(2) कोई व्यक्ति, राज्य अनुज्ञापन प्राधिकरण या केन्द्रीय अनुज्ञापन प्राधिकरण, जो भी मामला हो, द्वारा पारित आदेश से व्यथित है, तो वह ऐसे प्राधिकरण के आदेश की प्रति प्राप्त होने के पैंतालीस दिनों के भीतर, राज्य सरकार या केन्द्रीय सरकार, जो भी मामला हो, को अपील कर सकता है, और राज्य सरकार या केन्द्रीय सरकार, उक्त अपीलकर्ता को सुनने, के बाद आदेश की इसे पुष्ट करेगी या बदलेगी या संशोधित करेगी।"।

5. उक्त नियमों में, नियम 20 में,—

(क) सीमांत शीर्षक में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(ख) "श्रेणी क" शब्द और अक्षर, जहां भी यह हो, के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

6. उक्त नियमों में, नियम 31 के उपनियम (1) में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

7. उक्त नियमों में, नियम 36 के उपनियम (5) में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

8. उक्त नियमों में, दूसरी अनुसूची में, सारणी में, "श्रेणी क" शब्द और अक्षर, जहां भी यह हो, के स्थान पर "श्रेणी क (गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

9. उक्त नियमों में, तीसरी अनुसूची में, भाग 2 के अधीन, पैरा 1, खंड (1) के अंतर्गत, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

10. उक्त नियमों में, चौथी अनुसूची में, भाग 2 के अंतर्गत, पैरा (i) में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

11. उक्त नियमों की आठवीं अनुसूची की सारणी में, क्रम संख्यांक 7 और इससे संबंधित प्रविष्टियों के पश्चात्, निम्नलिखित अंतःस्थापित की जाएगी, अर्थात:—

क्रम सं.	चिकित्सा युक्तियों का वर्ग	छूट का विस्तार और शर्तें
"8.	श्रेणी क गैर-स्टेराइल और गैर-मापने वाले चिकित्सा युक्तियों का विनिर्माण	इन नियमों के अध्याय IV, VII, VIII और XI के सभी प्रावधान, इस शर्त के अधीन कि विनिर्माता इन नियमों के अध्याय III ख के अनुसार ऐसे युक्तियों का रजिस्ट्रीकरण कराएगा।
9.	श्रेणी क गैर-स्टेराइल और गैर-मापने वाले चिकित्सा युक्तियों का आयात	इन नियमों के अध्याय V, VII, VIII और XI के सभी प्रावधान, इस शर्त के अधीन कि आयातक इन नियमों के अध्याय III ख के अनुसार ऐसे युक्तियों का रजिस्ट्रीकरण कराएगा।" ।

12. उक्त नियमों के परिशिष्ट में,—

(क) प्ररूप एमडी-2 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(ख) प्ररूप एमडी-3 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(ग) प्ररूप एमडी-4 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(घ) प्ररूप एमडी-5 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ;

(ङ) प्ररूप एमडी-6 में, "श्रेणी क" शब्द और अक्षर के पश्चात्, "(गैर-स्टेराइल और गैर-मापन के अतिरिक्त)" शब्द और कोष्ठक अंतःस्थापित किए जाएँगे ।

[फा. सं. एक्स.11014/10/2022-डीआर]

डॉ. मनदीप के भण्डारी, संयुक्त सचिव

टिप्पण : चिकित्सा युक्ति नियम, 2017, राजपत्र में अधिसूचना सं. सा.का.नि. 78(अ), तारीख 31 जनवरी, 2017 द्वारा प्रकाशित किए गए थे और अधिसूचना सं. सा.का.नि. 754(अ), तारीख 30 सितंबर, 2022 द्वारा अंतिम बार संशोधित किए गए थे ।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 14th October, 2022

G.S.R. 777(E).—Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017 was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 710(E), dated the 20th September, 2022 in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of seven days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Official Gazette were made available to the public on 20th September, 2022;

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), and subject to *ex post* consultation with the Drugs Technical Advisory Board and consideration of suggestions of the Board in accordance with the provisions of the said sections, the Central Government hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:—

1. (1) These rules may be called the Medical Devices (Sixth Amendment) Rules, 2022.

   (2) These rules shall come into force on the date of their publication in the Official Gazette.

2. In the Medical Devices Rules, 2017 (hereinafter referred to as the said rules), in rule 13,—

   (a) in sub-rule (2), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

   (b) in sub-rule (3), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

3. In the said rules, in rule 14, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

4. In the said rules, after rule 19F, the following shall be inserted, namely:—

"CHAPTER IIIB

REGISTRATION OF CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICES

19G. Application of this Chapter.— (1) This Chapter shall be applicable to all non-sterile and non-measuring devices classified as Class A medical devices as per the First Schedule (herein in this chapter referred to as Class A non-sterile and non-measuring medical device).

(2) The medical devices referred to in sub-rule (1) shall be registered through an identified online portal established for the purpose.

19H. Uploading of information for registration.— (1) The manufacturer of a Class A non-sterile and non-measuring medical device shall upload the information specified in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The manufacturer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the manufacturer stating that the proposed device is a Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the manufacturer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the manufacturer shall self-certify to comply with the standards specified in these rules; and

(vi) an undertaking duly signed by the manufacturer stating that the information furnished by the applicant is true and authentic.

19-I. Registration number.— The registration number for a Class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19H on the Online System for Medical Devices established for this purpose.

19J. Import of Class A non-sterile and non-measuring medical device.— (1) Any person who intends to import any Class A non-sterile and non-measuring medical device shall upload the information in sub-rule (2) relating to that medical device for registration on the Online System for Medical Devices.

(2) The importer shall upload the following in the Online System for Medical Devices, namely:—

(i) name and address of importer and the name and address of the manufacturing site;

(ii) details of Class A non-sterile and non-measuring medical devices to be provided:

Generic name	Brand Name (if registered under the Trade Marks Act, 1999)	Model No (if any)	Intended use	Material of construction	Dimension (if applicable)	Shelf life (if applicable)
(1)	(2)	(3)	(4)	(5)	(6)	(7)

(iii) an undertaking from the importer stating that the proposed device is Class A non-sterile and non-measuring medical device, as per the First Schedule;

(iv) the importer shall self-certify that the product is conforming to the essential principles checklist of safety and performance of such devices;

(v) the importer shall self-certify to comply with the standards specified in these rules;

(vi) self-attested copy of the overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority or Free Sale Certificate issued by the National Regulatory Authority; and

(vii) an undertaking duly signed by the importer stating that the information furnished by the applicant is true and authentic.

19K. Registration number for import.— The registration number for import of a class A non-sterile and non-measuring medical device shall be generated after furnishing of the information in accordance with rule 19J on the Online System for Medical Devices established for this purpose.

19L. Maintainance of records.— (1) The manufacturer or, as the case may be, importer shall maintain the records relating to manufacturing or importing along with its sales or distribution.

(2) The manufacturer or, as the case may be, importer shall produce the records, labels, instructions for use, on request by Licensing Authorities.

(3) The Licensing Authorities may verify the records and documents referred to in sub-rule (2) at any point of time and investigate quality or safety related failures or complaints.

19M. Cancellation or suspension of registration.— (1) The State Licensing Authority or the Central Licensing Authority, as the case may be, may, after giving the registrant an opportunity to show cause as to why such an order should not be passed, by an order in writing stating the reasons thereof, cancel the registration number generated under the provisions of rule 19-I or rule 19K, or suspend it for such period as the Licensing Authority thinks fit, either wholly or in respect of any of the medical devices to which it relates, if in its opinion, the registrant has failed to comply with any of the provisions of the rules under this Chapter;

(2) Any person who is aggrieved by an order passed by the State Licensing Authority or the Central Licensing Authority, as the case may be, may, within forty-five days of the receipt of a copy of such order, prefer an appeal to the State Government or the Central Government, as the case may be, and the State Government or the Central Government, shall after giving the said appellant an opportunity of being heard, confirm, reverse or modify such order.**".**

5. In the said rules, in rule 20,—

(a) in the marginal heading, after the word and letter "Class A", the brackets and words "**(other than non-sterile and non-measuring)**" shall be inserted;

(b) after the word and letter "Class A", wherever they occur, the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

6. In the said rules, in rule 31, in sub-rule (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

7. In the said rules, in rule 36, in sub-rule (5), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

8. In the said rules, in the Second Schedule, in the table, for the word and letter "Class A", wherever they occur, the words and brackets "Class A (other than non-sterile and non-measuring)" shall be substituted.

9. In the said rules, in the Third Schedule, in Part II, in paragraph 1, in clause (1), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

10. In the said rules, in the Fourth Schedule, in Part II, in paragraph (i), after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

11. In the said rules, in the Eighth Schedule, in the table, after serial number 7 and the entries relating thereto, the following shall be inserted, namely:—

S.No.	Class of medical devices	Extent and conditions of exemptions
"8.	Manufacturing of Class A non-sterile and non-measuring medical devices	All provisions of Chapter IV, VII, VIII and XI of these rules, subject to the condition that the manufacturer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.
9.	Import of Class A non-sterile and non-measuring medical devices	All provisions of Chapter V, VII, VIII and XI of these rules, subject to the condition that the importer shall make registration of such devices, under the provisions of Chapter IIIB of these rules.".

12. In the said rules, in the Appendix,—

(a) in Form MD-2, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(b) in Form MD-3, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(c) in Form MD-4, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(d) in Form MD-5, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted;

(e) in Form MD-6, after the word and letter "Class A", the brackets and words "(other than non-sterile and non-measuring)" shall be inserted.

[F. No. X.11014/10/2022-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal rules were published in the Official Gazette *vide* notification number G.S.R. 78(E), dated the 31st January, 2017 and last amended *vide* notification number G.S.R. 754(E), dated the 30th September, 2022.

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MDR
CONSULTANTS

GET YOUR **MEDICAL DEVICE REGULATORY ASSISTANCE** FROM INDUSTRY EXPERTS

OUR SERVICES

CDSCO Registration

Medical Device Manufacturing Licence for Class A, B, C & D

Medical Device Import Licence

US FDA 510(K), MDSAP

CE Marking

ISO 13485:2016

Validation Studies

CONTACT US

9306468090

executive.ash@gmail.com

mdrconsultants.in