



प्रधान आयुक्त का कार्यालय, सीमा शुल्क ,अहमदाबाद

“सीमाशुल्क भवन ,”पहली मंजिल ,पुराने हाईकोर्ट के सामने ,नवरंगपुरा ,अहमदाबाद - 380 009.

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DIN:20260571MN0000813813

PREAMBLE

A	फ़ाइल संख्या/ File No.	:	CUS/RMSF/OBJ/19/2026-ICD-AHMD-CUS-COMMRTE-AHMEDABAD
B	कारण बताओ नोटिस संख्या-तारीख / Show Cause Notice No. and Date	:	The importer has requested for waiver of SCN
C	मूल आदेश संख्या/ Order-In-Original No.	:	19/ADC/SR/O&A/HQ/2026-27
D	आदेश तिथि/ Date of Order-In-Original	:	12.05.2026
E	जारी करनेकी तारीख/ Date of Issue	:	12.05.2026
F	द्वारापारित/ Passed By	:	Shravan Ram, Additional Commissioner, Customs Ahmedabad.
G	आयातक का नाम औरपता / Name and Address of Importer	:	M/s. Lab Medica Systems Pvt. Ltd., 705, Sakar-5, Near Mithakhali Railway Crossing, Off C G Road, Ahmedabad- 380009. (IEC No. 0813002257)
(1)	यह प्रति उन व्यक्तियों के उपयोग के लिए निःशुल्क प्रदान की जाती है जिन्हे यह जारी की गयी है।		
(2)	कोई भी व्यक्ति इस आदेश से स्वयं को असंतुष्ट पाता है तो वह इस आदेश के विरुद्ध अपील इस आदेश की प्राप्ति की तारीख के 60 दिनों के भीतर आयुक्त कार्यालय, सीमा शुल्क(अपील), चौथी मंजिल, हडको भवन, ईश्वर भुवन मार्ग, नवरंगपुरा, अहमदाबाद में कर सकता है।		
(3)	अपील के साथ केवल पांच (5.00) रुपये का न्यायालय शुल्क टिकिट लगा होना चाहिए और इसके साथ होना चाहिए:		
(i)	अपील की एक प्रति और;		
(ii)	इस प्रति या इस आदेश की कोई प्रति के साथ केवल पांच (5.00) रुपये का न्यायालय शुल्क टिकिट लगा होना चाहिए।		
(4)	इस आदेश के विरुद्ध अपील करने इच्छुक व्यक्ति को 7.5 % (अधिकतम 10 करोड़) शुल्क अदा करना होगा जहां शुल्क या इयूटी और जुर्माना विवाद में है या जुर्माना जहां इस तरह की दंड विवाद में है और अपील के साथ इस तरह के भुगतान का प्रमाण पेश करने में असफल रहने पर सीमा शुल्क अधिनियम, 1962 की धारा 129 के प्रावधानों का अनुपालन नहीं करने के लिए अपील को खारिज कर दिया जायेगा।		

BRIEF FACTS OF THE CASE

M/s. Lab Medica Systems Pvt. Ltd. (IEC No. 0813002257), having address at 705, Sakar-5, Near Mithakhali Railway Crossing, Off C. G. Road, Ahmedabad-380009, filed B/E Nos. 6331447/ 16.12.2025 and 7215853/ 30.01.2026 for import of total 175 nos. of “Optical Instruments- Auto Lensmeter TL-6900” under declared CTH 90314900, from their supplier, Ningbo Luneau Optical Equipment Co. Ltd., China, having total declared total assessable value of Rs.64,26,168/- and duty of Rs.17,82,298/-.

2. As per Para 3(zb) of Medical Devices Rules 2017, “*medical device means,-*
- (A) *substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i),*
- (B) *substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),*
- (C) *devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act.”*
- 2.1. Further, as per Para 34(1), “*an authorised agent having licence to manufacture for sale or distribution or wholesale licence for sale or distribution under these rules, shall make an application for grant of import licence for medical device to the Central Licensing Authority through an identified online portal of the Ministry of Health and Family Welfare in the Central Government in Form MD-14 for obtaining a licence.”*
- 2.2. Further, as per Para 36(1), “*after examination of documents furnished with the application under sub-rule (1) of rule 34 and on the basis of the inspection report, if inspection has been carried out, the Central Licensing Authority may, on being satisfied, grant licence in Form MD-15 or, may reject such application for which reasons shall be recorded in writing, within a period of nine months from the date of application.”*
- 2.3. In view of the above, it appears that an MD-15 license issued by CDSCO is required for import of any medical device in India.
- 2.4. As per CDSCO Notice F. No. 29/Misc./03/2020-DC(187) dated 09.08.2021 regarding classification of medical device pertaining to Ophthalmology under the provisions of Medical Devices Rules 2017, Automated lensmeter (Diopotometer) (at Sr. No. 5), with intended use as “*an ophthalmic instrument designed to measure the focusing power (dioptric power) and other optical characteristics of a spectacle lens, contact lens, or prism*”, has been classified as Class A medical device.
- 2.5. As per CDSCO Notification No. G.S.R. 777(E) dated 14.10.2022, import of Class A non-sterile and non-measuring medical devices is allowed only on registration of the medical device on CDSCO website. Since the subject item appeared to be a measuring medical device, it appeared that MD-15 license was required for its import.
- 2.6. Assistant Drugs Controller, Old Air Cargo Complex, Ahmedabad vide email dated 06.02.2026 informed that the subject item was a measuring device and thus import license (MD-15) for class A medical device was applicable.
3. Accordingly, queries were raised to the importer to submit MD-15 license required for import of the subject medical device, in response to which, they submitted that the imported item was not a medical device but an optical instrument for measurement of optical glasses and not an ophthalmic instrument for eyesight testing. They did not submit any valid MD-15 license for the subject item.
4. In view of the above, it appears that total 175 nos. of Auto Lensmeter TL-6900 imported by Lab Medica Systems Pvt. Ltd. (IEC No. 0813002257) vide B/E Nos. 6331447/ 16.12.2025 and 7215853/ 30.01.2026, having total declared assessable value of Rs.64,26,168/-, which are a Class A ‘measuring’ medical device requiring MD-15 license for its import, as specified in the CDSCO Notice dated 09.08.2021 and as confirmed by Assistant Drugs Controller, Ahmedabad, imported without a valid MD-15 license in contravention of Medical Devices Rules 2017, are liable for absolute confiscation under Section 111(d) of Customs Act 1962.
- 4.1. The importer, for their acts of omission and commission, is consequently liable for penalty under Section 112 of the Customs Act 1962.

4.2. Since the goods are liable for absolute confiscation, they are liable to be disposed by way of destruction; if the same are redeemed to the importer for re-export, the importer is liable to pay redemption fine under Section 125 of the Customs Act 1962.

RECORD OF PERSONAL HEARING:

5. Shri Sanjay Raval, Director of Lab Medica Systems Pvt. Ltd., submitted that the product imported by them falls under Class A Medical Device, and for this category of devices, MD-15 license is not required; that the only requirement for this class of device is of registration on CDSCO website; that this registration has already been done. He therefore requested to clear the consignment at the earliest.

5.1. He further appeared for PH on 25.03.2026, wherein he reiterated his submissions made vide their letter dated 28.02.2026. He further requested for early permission to send the goods back to origin without any penalty.

IMPORTER'S SUBMISSIONS:

6. The importer vide letter dated 28.02.2026 submitted that the instrument Auto Lensmeter had been included by CDSCO within the notified list of medical devices, however, in practical and technical terms, the same was primarily used in optical retail shops and spectacle manufacturing units for measurement and verification of spectacle lenses, it was not used on patients, nor for clinical diagnosis in hospitals, and it functioned as an optical measuring instrument. They had classified the subject item as an optical instrument under CTH 9031 (18% IGST) instead of as a medical device under CTH 9018 (5% IGST). They did not want any Personal Hearing or Show Cause Notice in the matter. They requested permission to re-export the consignments back to origin without penalty. They also requested to allow refund of customs duty of Rs.17,82,298/- already paid for the two consignments.

DISCUSSION AND FINDINGS:

7. I find that the importer, Lab Medica Systems Pvt. Ltd., filed B/E Nos. 6331447/ 16.12.2025 and 7215853/ 30.01.2026 for import of total 175 nos. of "*Optical Instruments- Auto Lensmeter TL-6900*" from China, having total declared total assessable value of Rs. 64,26,168/- and duty of Rs.17,82,298/-.

8. I find that the imported item Auto Lensmeter has been specified as a Class A Medical Device in the CDSCO Notice dated 09.08.2021, and has been confirmed as a 'measuring' Class A Medical Device by Assistant Drugs Controller, Ahmedabad in their email correspondence. Thus, the subject item requires an MD-15 license issued by CDSCO for its import.

9. I further find that even though the subject item has been declared as an Optical Instrument and is primarily used in optical retail shops and spectacle manufacturing units for measurement and verification of spectacle lenses, and not used on patients, nor for clinical diagnosis in hospitals, there is no doubt that it is a medical device i.e. instrument Auto Lensmeter had been included by CDSCO within the notified list of medical devices, which is a restricted item for import requiring an MD-15 license. Since the importer is not in possession of the same, I find that the goods have been imported in contravention of Medical Devices Rules 2017, and are thus liable for absolute confiscation under Section 111(d) of Customs Act 1962.

9.1. Further, I find the importer for their acts of omission and commission, consequently liable for penalty under Section 112 of the Customs Act 1962.

9.2. I find that the goods being regulated medical device imported without valid license, cannot be sold in the domestic market. They are thus liable for absolute confiscation and to be disposed by way of destruction.

9.2. I find that the importer has requested for permission for re-export of the goods; the same can be allowed to the importer, but only on payment of redemption fine under Section 125 of the Customs Act 1962.

9.3. I also find that since the goods cannot be allowed for home consumption, duty paid for the subject B/Es amounting to Rs.17,82,298/- is liable to be refunded to the importer. This amount may be adjusted against the fine/ penalty imposed vide this order.

10. The find that the importer has requested for waiver of show cause notice. I therefore proceed to adjudicate this case on the basis of available records and on merit.

11. In view of the above discussion and findings, I pass the following order:

ORDER

(1) I hold the goods imported by Lab Medica Systems Pvt. Ltd. vide B/E Nos. 6331447/ 16.12.2025 and 7215853/ 30.01.2026 having total declared total assessable value of Rs.64,26,168/-, liable for confiscation under Section 111(d) of Customs Act 1962.

(2) I impose a penalty of **Rs.25,000/- (Rupees Twenty-Five Thousand Only)** on the importer Lab Medica Systems Pvt. Ltd. under Section 112 of the Customs Act 1962.

(3) I give an option to redeem the subject goods for re-export only on payment of Redemption Fine of **Rs.25,000/- (Rupees Twenty-Five Thousand Only)** under Section 125 of the Customs Act 1962.

(4) I order for refund of duty of Rs.17,82,298/- paid by the importer for B/E Nos. 6331447/ 16.12.2025 and 7215853/ 30.01.2026.

12. This order is issued without any prejudice to any action that may be taken under any section of the Customs Act 1962 or any other law/ act for the time being in force.

(Shravan Ram)
Additional Commissioner,
Customs, Ahmedabad

DIN:20260571MN0000813813

F. No. CUS/RMSF/OBJ/19/2026-ICD-AHMD-CUS-COMMRTE-AHMEDABAD Date:12.05.2026

To,

M/s. Lab Medica Systems Pvt. Ltd. (IEC No. 0813002257),
705, Sakar-5, Near Mithakhali Railway Crossing,
Off C G Road, Ahmedabad- 380009.

Copy to:

1. The Asst./Dy. Commissioner of Customs (Review Cell), Customs, HQ, Ahmedabad.
2. The Asst./Dy. Commissioner of Customs (EDI/Systems), Customs, HQ, Ahmedabad.
3. The Asst./Dy. Commissioner of Customs, ICD Khodiyar, Ahmedabad.
4. Office Copy.
5. Guard File