कार्यालय: प्रधान आयुक्त सीमाशुल्क, मुन्द्रा,
सीमाशुल्क भवन, मुन्द्रा बंदरगाह, कच्छ, गुजरात- 370421
OFFICE OF THE PRINCIPAL COMMISSIONER OF CUSTOMS:
CUSTOM HOUSE, MUNDRA PORT, KUTCH, GUJARAT-370421.
PHONE : 02838-271426/271163 FAX :02838-271425
E-mail id- adj-mundra@gov.in

A. File No.	:	GEN/ADJ/ADC/662/2026-Adjn-O/o Pr Commr-Cus-Mundra
B. SCN No.	:	150/2026-27/ADC/ZDC/MCH
C. Date of Issue		14.09.2026
D. Passed by	:	**Dipak Zala,** Additional Commissioner of Customs, Customs House, AP&SEZ, Mundra.
E. Noticee(s)/Importer	:	M/s Primo International (India) (IEC-BCBPG7174B)

(Show Cause Notice under Section 124 of the Customs Act, 1962)

Whereas it appears that:

M/s. Primo International (India), located at KH. No. 16/9, First Floor, Gali No., Burari Road, Swaroop Nagar, North West Delhi-110042, holding IEC No. BCBPG7174B [hereinafter referred to as **"importer"** for the sake of brevity] is engaged in the import of medical examination gloves from Malaysia and Thailand.

Intelligence developed by officers of the Directorate of Revenue Intelligence (DRI), Trivandrum Regional Unit, revealed that M/s Primo International (India), holder of **IEC No. BCBPG7174B,** KH. NO. 16/9, First Floor, Gali No, Burari Road, Swaroop Nagar, North West Delhi - 110042, was

importing medical examination gloves from Malaysia and Thailand. The intelligence indicated that the importer was claiming an ineligible IGST rate of 12% by wrongly classifying medical/surgical examination gloves under CTH 40151900 (Other Gloves) instead of the correct classification under CTH 40151200 (Gloves for Medical, Surgical, Dental or Veterinary purposes), and/or was not complying with the mandatory requirements under the Medical Devices Rules, 2017, as notified under the Drugs & Cosmetics Act, 1940.

2. INVESTIGATION

2.1 Analysis of Import data.

Data analytics undertaken by the Directorate of Revenue Intelligence identified that M/s Primo International (India) was misclassifying medical examination gloves under CTH 40151900 (Other Gloves) in their import declarations. Detailed analysis of Bills of Entry filed from 14.10.2022 onwards revealed systematic incorrect classification, wherein medical gloves that should have been classified under the specific CTH 40151200 (Gloves for Medical, Surgical, Dental or Veterinary purposes) introduced vide Finance Act, 2021, were instead being declared under the residual category CTH 40151900. Significantly, while the importer declared the product description as 'Medical Examination Gloves' or 'Examination Gloves' in the Bills of Entry—thereby clearly acknowledging the medical nature of the goods—they simultaneously classified the same goods under CTH 40151900 (Other Gloves), revealing a deliberate contradiction. This misclassification enabled the importer to pay IGST @ 12% when the classification of goods under the CTH 40151900 attracted 18%, resulting in suspected evasion of differential duty @ 6%/ non-compliance of the Medical Devices Rules, 2017.

2.2. Communication with M/s Primo International (India)

A letter dated 16.04.2025 bearing DIN -- 202504DDJ100005505F1 was issued to M/s Primo International (India) to furnish the pertinent Bills of Entry and concomitant Invoices and data sheets comprising all the technical specifications of the items they have imported under the CTH 40151900 from 01.10.2022 and also to authorize a competent person who is aware of the issue

to tender a statement under Section 108 of the Customs Act 1962 on 21.05.2025 **(RUD-01**). Shri. Sahil Gupta, vide email dated 14.05.2025 had acknowledged the receipt of the letter and assured the submission of documents within 5 days **(RUD-02)**. In furtherance of the persistent follow-ups from this office M/s Primo International (India) vide email dated 27.05.2025 had submitted their import related documents to this office for scrutiny **(RUD-03)**.

2.3. Scrutiny of the Bills of Entry filed w.e.f 14.10.2022 and other import related documents.

A total of 29 Bills of Entry were scrutinized during the period from 14.10.2022 to 30.04.2025 **(ANNEXURE – I)** where M/s Primo International (India) has been importing medical examination gloves and classifying them under CTH 40151900 (Other Gloves) whereas medical gloves should have been rightly classified under the specific CTH 40151200 (Gloves for Medical, Surgical, Dental or Veterinary purposes) introduced vide Finance Act, 2021. On scrutiny of the said Bills of Entry, it was observed that M/s Primo International (India) had imported and distributed medical examination gloves as well as non-medical examination gloves. The medical examination gloves thus imported were distributed to dealers in the health care sector across North India, including hospitals and government agencies. The importer had obtained CDSCO registration as mandated by the Medical Devices Rules 2017, for the following overseas suppliers:

SL No	**Supplier**	**CDSCO Reg No**
1	M/s. Professional Latex SDN BHD	Profes-MYS/I/MD/014418
2	M/s. Stri Trang Gloves	SriTa-THA/I/MD/014638
3	M/s. Raybell Engineering SDN BHD	RAYBELL-MYS/I/MD/ 016020
4	M/s. Ace Glove(M) SDN. BHD	ACEGL-MYS/I/MD/013733
5	M/s. Qube Medical Products SDN BHD	QUBEM-MYS/I/MD/ 012558

However it was noticed that in three Bills of Entry, the firm had imported medical examination gloves with an aggregate value of **Rs. 1,80,26,374/- (Rupees One crore eighty lakh twenty-six thousand three hundred and seventy-four only)** under CTH 40151900 from overseas suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD, who were not registered by the firm under CDSCO **(ANEXURE-II).**

2.4. A Summons bearing reference number CBIC-DIN-202511DDJ10000555CD9 dated 05.11.2025 **(RUD-04)** was issued to Shri. Sahil Gupta, Director, M/s Primo International (India), under Section 108 of the Customs Act, 1962, directing him to appear before the Senior Intelligence Officer, DRI, Trivandrum Regional Unit on 05.11.2025 for recording his voluntary statement in connection with the investigation pertaining to import of gloves by ineligible claim of IGST rate of 12%/ non-compliance of Medical Devices Rules-2017.

2.5. Statement of Shri. Sahil Gupta, Director, M/s Primo International (India)

Shri. Sahil Gupta, Director, M/s Primo International (India), appeared before the Senior Intelligence Officer, DRI, Trivandrum Regional Unit on 05.11.2025 and gave his voluntary statement under Section 108 of the Customs Act, 1962 **(RUD-05)** wherein he interalia stated that:

1. M/s Primo International (India) was established in the year 2020. The firm is involved in importing and distributing medical examination gloves as well as non-medical examination gloves to dealers in the health care sector across North India, including hospitals such as Maharaja Agrasen, Delhi, NKS Hospital etc. They also supply medical examination gloves to various government agencies under OEM category.
2. Their major overseas suppliers for medical examination gloves are: (a) M/s. Professional Latex SDN BHD (CDSCO Reg. Profes-MYS/I/MD/014418), (b) M/s. Stri Trang Gloves (CDSCO Reg. SriTa-THA/I/MD/014638), (c) M/s. Raybell Engineering SDN BHD (CDSCO Reg. RAYBELL-MYS/I/MD/016020), (d) M/s. Ace Glove(M) SDN.

BHD. (CDSCO Reg. ACEGL-MYS/I/MD/013733), and (e) M/s. Qube Medical Products SDN BHD (CDSCO Reg. QUBEM-MYS/I/MD/012558).

3. In a few Bills of Entry v.i.z 3012649 dated 22.10.2022, 6445018 dated 01.11.2024 and 9145969 dated 27.03.2025 the firm had imported gloves under CTH 4015 1900 from overseas suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD, paying 12% IGST. Shri. Sahil Gupta also stated that the firm had imported medical gloves from these suppliers for which the suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD were not registered under CDSCO. The firm assured that they are willing to pay the differential IGST along with applicable interest.
4. During the relevant period both medical and non-medical gloves have been imported. When imported goods were declared under CTH 40151900 with a product description “Medical/ Examination gloves”, they were asked to explain why they did not declare the goods under CTH 40151200. Shri. Sahil Gupta stated that he had classified a few of his imports in CTH 4015 1900 as normal industrial practice which his CHA was following.
5. The firm classifies goods in the same HSN in their sales invoices and GST returns as per the corresponding import documents.
6. Regarding fulfillment of conditions under Medical Devices Rules, 2017 for the import of medical examination gloves/surgical gloves, he stated that they have obtained the CDSCO registration for all the overseas suppliers except which they have missed out as stated in Sl No 3 above.
7. Three consignments (BE No. 4191565 dated 26.06.2024, 5151672 dated 20.08.2024 and 8158905 dated 03.02.2025) wherein medical examination gloves were declared under CTH 4015 1900 underwent ADC examination and were subsequently cleared.
8. In his final statement, he clarified that none of his consignments declared under the CTH 40151200 and 40151900 have been rejected by the proper officer after examination till date.

3. ANALYSIS AND FINDINGS

The investigation has revealed that M/s Primo International (India) imported medical examination gloves from multiple overseas suppliers during the period from 14.10.2022 to 30.04.2025, involving a total of 29 Bills of Entry wherein the goods were classified under CTH 40151900 (Other Gloves) instead of the specific classification CTH 40151200 (Gloves for Medical, Surgical, Dental or Veterinary purposes) introduced vide Finance Act, 2021 with effect from 01.01.2022. The analysis of available evidence, import documents, CDSCO registration status, product declarations in Bills of Entry, and statements of the importer necessitates a differentiated approach in assessing the nature of violations and liability arising from these imports based on the regulatory compliance status of overseas suppliers.

3.1. Imports from CDSCO-Registered Suppliers

With respect to medical examination gloves imported from overseas suppliers who possess valid CDSCO registration certificates—namely M/s. Professional Latex SDN BHD (CDSCO Reg. Profes-MYS/I/MD/014418), M/s. Stri Trang Gloves (CDSCO Reg. SriTa-THA/I/MD/014638), M/s. Raybell Engineering SDN BHD (CDSCO Reg. RAYBELL-MYS/I/MD/016020), M/s. Ace Glove(M) SDN. BHD. (CDSCO Reg. ACEGL-MYS/I/MD/013733) and M/s. Qube Medical Products SDN BHD (CDSCO Reg. QUBEM-MYS/I/MD/012558) **(RUD-06)** — the contention of the importer that these imports constituted medical/examination gloves of medical grade quality can be accepted based on the following considerations:

i) the imported goods have already been cleared by Customs authorities, sold in the market to end-users including hospitals, government health agencies under OEM category, and distributors in the medical field as admitted by Shri. Sahil Gupta in his statement dated 05.11.2025 under Section 108 of the Customs Act, 1962, the sample invoices submitted and consequently the physical goods no longer exist in their original form for examination and testing.

ii) given that consumption of these gloves has already occurred in healthcare settings, as evidenced by the GST invoices submitted, establishing a one-to-one correlation to prove that specific consignments contained non-medical gloves is practically impossible and would amount to an unreasonable evidentiary burden.

iii) three consignments (BE No. 4191565 dated 26.06.2024, BE No. 5151672 dated 20.08.2024, and BE No. 8158905 dated 03.02.2025) **(RUD-07)** wherein medical examination gloves were declared under CTH 40151900 underwent Assistant Drug Controller (ADC) examination and were subsequently cleared by the proper officer, demonstrating that upon physical examination, the goods were found acceptable for clearance.

iv) as admitted by the importer, none of their consignments declared under CTH 40151200 or CTH 40151900 have been rejected by the proper officer after examination till date, indicating that physical examination did not reveal any non-conformity with declared descriptions.

Given the findings of the investigation, it is observed that the importer's contention that medical examination gloves imported from **CDSCO-registered suppliers** were genuinely meant for medical, surgical, dental, or veterinary purposes appears to be **factually correct**, in as much as the investigation could not reveal any cogent evidence to prove the contrary. However, it is noted that there exists **misclassification** of these goods under incorrect **CTH 40151900** instead of the correct **CTH 40151200** (applicable from 01.01.2022 onwards as per Finance Act, 2021).

While the misclassification under incorrect CTH constitutes a technical irregularity that requires correction in future imports, the imports of medical examination gloves from **CDSCO-registered suppliers** do not attract any liability for:

- Confiscation under Section 111 of the Customs Act, 1962

- Penalty under Sections 112 (a) & 112 (b) of the Customs Act, 1962
- Recovery of differential duty or interest

3.2. Imports from Non-CDSCO-Registered Suppliers

With respect to medical examination gloves imported from overseas suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD in three Bills of Entry **(ANEXURE-II)**, with an aggregate value of **Rs. 1,80,26,374/- (Rupees One crore eighty lakh twenty-six thousand three hundred and seventy-four only)** who are not registered with CDSCO, a fundamentally different legal position emerges. The importer has declared the product description as 'Medical Examination Gloves' or 'Examination Gloves' in the Bills of Entry for imports from these non-CDSCO-registered suppliers, and this declaration is further reinforced and confirmed by Shri. Sahil Gupta's statement dated 05.11.2025 under Section 108 of the Customs Act, 1962, wherein he admitted that ***"the firm had imported medical gloves from these companies."*** Having thus declared and admitted that these goods were 'medical gloves' or 'medical examination gloves', based on the importer's own declarations in the Bills of Entry and admissions in the recorded statement, **these goods can only be treated and assessed as 'medical examination gloves' or 'medical devices' for all legal purposes.**

Once it is established that the goods imported from M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD were 'medical examination gloves' or 'medical devices' as per the importer's own declaration and admission, the legal framework governing such imports becomes applicable. "Medical examination gloves are classified as 'medical devices' under **Rule 4 read with Part I of the First Schedule** of the Medical Devices Rules, 2017, which were notified by the Central Government in exercise of powers under **Sections 12 and 33** of the Drugs and Cosmetics Act, 1940. By virtue of Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940, medical devices fall within the statutory definition of 'drug' as they are devices intended to be used for diagnosis, treatment, mitigation, or prevention of disease. **Section 10** of the Drugs and Cosmetics Act, 1940 expressly prohibits the import of drugs and cosmetics (including medical devices) that are not of standard quality or that are misbranded,

adulterated, or spurious, except under and in accordance with the conditions of a license issued under the rules made under this Act. This statutory prohibition is further operationalized through **Rule 34, Rule 36, and Rule 38** of the Medical Devices Rules, 2017, which mandate that medical devices can only be imported if the **authorized agent** holds a valid **import license** from the Central Drugs Standard Control Organisation (CDSCO), and the overseas manufacturing site may be subject to inspection. The import of medical devices without such valid CDSCO import license constitutes a direct violation of **Section 10** read with **Section 18** of the Drugs and Cosmetics Act, 1940, which is 'a law for the time being in force' imposing a prohibition on such import.

"The Customs Act, 1962 provides the mechanism for treating such goods imported in violation of prohibitions imposed by other laws. Section 2(33) of the Customs Act, 1962 defines 'prohibited goods' as: *'prohibited goods' means any goods the import or export of which is subject to any prohibition under this Act or any other law for the time being in force but does not include any such goods in respect of which the conditions subject to which the goods are permitted to be imported or exported have been complied with.*

Consequently, Section 111(d) of the Customs Act, 1962 becomes applicable, which provides: *'The following goods brought from a place outside India shall be liable to confiscation: (d) any goods which are imported or attempted to be imported... contrary to any prohibition imposed by or under this Act or any other law for the time being in force.'*

The medical examination gloves imported without valid **CDSCO registration** and **import license** from overseas suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD, having been imported contrary to the prohibition imposed by **Section 10 read with Section 18** of the Drugs and Cosmetics Act, 1940 and **Chapter III-B** of the Medical Devices Rules, 2017 as inserted vide **GSR 102(E) dated 11th February 2020** (which is 'any other law for the time being in force'), are therefore liable for confiscation under Section 111(d) of the Customs Act, 1962 as 'prohibited goods'."

The importer's contention that these gloves imported from overseas suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHDwere classified under CTH 40151900 as 'normal industrial practice' followed by their Customs House Agent **cannot be accepted as a valid defense or justification** for multiple compelling reasons:

"Section 46(4) and Section 46(4A) of the Customs Act, 1962 cast a personal and non-delegable responsibility upon the importer:

i) Under **Section 46(4)**, the importer must make and subscribe to a **declaration as to the truth of the contents** of the bill of entry and produce the invoice and such other prescribed documents in support thereof.

ii) Under **Section 46(4A)**, the importer who presents a bill of entry shall ensure:

- **(a)** the **accuracy and completeness** of the information given therein;
- **(b)** the **authenticity and validity** of any document supporting it; and
- **(c) compliance with the restriction or prohibition**, if any, relating to the goods **under this Act or under any other law for the time being in force**.

This statutory responsibility is **personal to the importer** and **cannot be transferred to or absolved by the actions of a Customs House Agent**. The importer remains ultimately accountable for ensuring truthfulness, accuracy, authenticity of documents, and compliance with all applicable restrictions and prohibitions, including those imposed under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017.

Given these factors, it appears that medical examination gloves imported from non-CDSCO-registered suppliers M/s. MTK Medic Co. Ltd. and M/s. Satnam SDN BHD in three Bills of Entry **(ANEXURE-II)**, with an aggregate value of **Rs. 1,80,26,374/- (Rupees One crore eighty lakh twenty-six thousand three hundred and seventy-four only) constitute prohibited**

goods liable for confiscation under Section 111(d) of the Customs Act, 1962.

4. PROVISIONS OF LAW

The relevant provisions of law relating to import of goods in general, the Policy & Rules relating to import, the liability of the goods to confiscation and rendering persons concerned liable to penalty for illegal importation under the provisions of the Foreign Trade (Development and Regulation) Act, 1992, Foreign Trade (Regulation) Rules, 1993, the Customs Act, 1962, the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017, and any other law for the time being in force so far as they relate to the facts and circumstances of the subject matter, are summarized as under:

4.1 Foreign Trade (Development & Regulation) Act, 1992 and Foreign Trade (Regulation) Rules, 1993

(A) Section 11(1) of the Foreign Trade (Development and Regulation) Act, 1992:

As per Section 11(1) of the Foreign Trade (Development and Regulation) Act, 1992, *no export or import shall be made by any person except in accordance with the provisions of this Act, the rules and orders made thereunder and the export and import policy for the time being in force.*

(B) Rule 11 of the Foreign Trade (Regulation) Rules, 1993:

As per Rule 11 of the Foreign Trade (Regulation) Rules, 1993, *on importation into any Customs port of any goods, whether liable to duty or not, the owner of such goods shall in the Bill of Entry state the value, quality and description of such goods to the best of his knowledge and belief and shall subscribe a declaration of the truth of such statement at the foot of such Bill of Entry.*

4.2 The Customs Act, 1962

(A) Section 2(33) - Definition of "Prohibited Goods":

Section 2(33) of the Customs Act, 1962 defines "prohibited goods" as any goods the import or export of which is subject to any prohibition under this Act or any other law for the time being in force but does not include any such goods in respect of which the conditions subject to which the goods are permitted to be imported or exported have been complied with.

(B) Section 46(4) - Declaration by Importer:

The importer while presenting a Bill of Entry shall at the foot thereof make and subscribe to a declaration as to the truth of the contents of such Bill of Entry and shall, in support of such declaration, produce to the proper officer the invoice, if any, and such other documents relating to the imported goods as may be prescribed.

(C) Section 46(4A) - Obligations of Importer:

The importer who presents a Bill of Entry shall ensure the following, namely:

- *(a) the accuracy and completeness of the information given therein;*
- *(b) the authenticity and validity of any document supporting it; and*
- *(c) compliance with the restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force.*

This statutory responsibility is personal to the importer and cannot be transferred to or absolved by the actions of a Customs House Agent.

(D) Section 111 - Confiscation of improperly imported goods:

The following goods brought from a place outside India shall be liable to confiscation:

(d) any goods which are imported or attempted to be imported or are brought within the Indian customs waters for the purpose of being imported, contrary to any prohibition imposed by or under this Act or any other law for the time being in force;

(E) Section 112 - Penalty for improper importation of goods:

Any person,-

(a) who, in relation to any goods, does or omits to do any act which act or omission would render such goods liable to confiscation under section 111, or abets the doing or omission of such an act, or

(b) who acquires possession of or is in any way concerned in carrying, removing, depositing, harbouring, keeping, concealing, selling or purchasing, or in any other manner dealing with any goods which he knows or has reasons to believe are liable for confiscation under section 111,

shall be liable for penalty.

(F) Section 124 - Issue of show cause notice before confiscation:

No order confiscating any goods or imposing any penalty on any person shall be made under this Chapter unless the owner of the goods or such person:

- *(a) is given a notice in writing informing him of the grounds on which it is proposed to confiscate the goods or to impose a penalty;*
- *(b) is given an opportunity of making a representation in writing within such reasonable time as may be specified in the notice against the grounds of confiscation or imposition of penalty mentioned therein; and*
- *(c) is given a reasonable opportunity of being heard in the matter.*

(G) Section 125 of the Customs Act, 1962

- *Option to pay fine in lieu of confiscation.—(1) Whenever confiscation of any goods is authorised by this Act, the officer adjudging it may, in the case of any goods, the importation or exportation whereof is prohibited under this Act or under any other law for the time being in force, and shall, in the case of any other goods, give to the owner of the goods 4[or, where such owner is not known, the person from whose possession or custody such goods have been seized,] an option to pay in lieu of confiscation such fine as the said officer thinks fit:*
- *Provided that where the proceedings are deemed to be concluded under the proviso to sub-section (2) of section 28 or under clause (i) of sub-section (6) of that section in respect of the goods which are not prohibited or restricted, the provisions of this section shall not apply:*
- *Provided further that], without prejudice to the provisions of the proviso to sub-section (2) of section 115, such fine shall not exceed the market price of the goods confiscated, less in the case of imported goods the duty chargeable thereon.*
- *(2) Where any fine in lieu of confiscation of goods is imposed under sub-section (1), the owner of such goods or the person referred to in sub-section (1), shall, in addition, be liable to any duty and charges payable in respect of such goods.]*

- *(3) Where the fine imposed under sub-section (1) is not paid within a period of one hundred and twenty days from the date of option given thereunder, such option shall become void, unless an appeal against such order is pending.*

Explanation.—For removal of doubts, it is hereby declared that in cases where an order under sub-section (1) has been passed before the date on which the Finance Bill, 2018 receives the assent of the President and no appeal is pending against such order as on that date, the option under said sub-section may be exercised within a period of one hundred and twenty days from the date on which such assent is received.]

4.3. Medical Devices Rules, 2017

Medical examination gloves are classified as 'medical devices' under Rule 4 read with Part I of the First Schedule of the Medical Devices Rules, 2017, which were notified by the Central Government vide G.S.R. 78(E) dated 31st January 2017 in exercise of powers under Sections 12 and 33 of the Drugs and Cosmetics Act, 1940, and came into force with effect from 1st January 2018.

By virtue of Section 3(b)(iv) of the Drugs and Cosmetics Act, 1940, medical devices fall within the statutory definition of 'drug' as they are devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals.

The import of medical devices into India is subject to specific regulatory requirements under Chapter III-B (inserted vide GSR 102(E) dated 11th February 2020, effective from 1st April 2020), Rule 34, Rule 36, and Rule 38 of the Medical Devices Rules, 2017, read with Section 10 and Section 18 of the Drugs and Cosmetics Act, 1940. The Central Drugs Standard Control Organisation (CDSCO) is the regulatory authority for:

- (a) Registration of medical devices (under Chapter III-B); and
- (b) Grant of import licenses for import of medical devices (under Rules 34, 36 and 38).

The import of medical examination gloves without valid CDSCO registration and import license held by an authorized agent constitutes a violation of Section 10 read with Section 18 of the Drugs & Cosmetics Act, 1940 and Chapter III-B, Rule 34, Rule 36, and Rule 38 of the Medical Devices Rules, 2017, making such goods 'prohibited goods' under Section 2(33) of the Customs Act, 1962 and liable for confiscation under Section 111(d) of the Customs Act, 1962 which renders the importer liable for penalty under Section 112 (a) & Section 112 (b) of the Customs Act, 1962.

5. CONFISCATION AND PENALTY

In view of the evidence gathered during investigation and the foregoing provisions of law the following may please be considered for issue of Show Cause Notice under Section 124 of the Customs Act 1962:

- The medical examination gloves imported by **M/s Primo International (India)**from **M/s MTK Medic Co. Ltd.** and **M/s Satnam SDN BHD** as detailed in ANNEXURE-II are **prohibited goods** and liable for **confiscation** under Section 111(d) of the Customs Act, 1962;
- The importer, **M/s Primo International (India)**, is liable for **penalties** under Section 112 (a) & Section 112 (b) of the Customs Act, 1962;
- The importer has violated fundamental statutory obligations under Section 46(4) and Section 46(4A) of the Customs Act, 1962, Section 11(1) of the FT(DR) Act, 1992, and Rule 11 of the FT(R) Rules, 1993;
- The importer's conduct demonstrates **willful and deliberate contravention** with mala-fide intention to circumvent the regulatory requirements mandated under the Medical Devices Rules 2017.

6. Now, therefore, M/s Primo International (India), KH. NO. 16/9, First Floor, Gali No, Burari Road, Swaroop Nagar, North West Delhi - 110042 are hereby called upon to show cause in writing to the Additional Commissioner of Customs, Customs House, Mundra having office situated at office of the Pr. Commissioner of Customs, 5B, Port User Building, Adani Ports & SEZ, Mundra, Kutch, Gujarat – 370421 within 30 (thirty) days from the date of receipt of the notice, as to why:

i. The medical examination gloves imported from **non-CDSCO-registered suppliers**, namely:

- **M/s MTK Medic Co. Ltd.** and
- **M/s Satnam SDN BHD**

as detailed in **ANNEXURE-II**, with an aggregate assessable value of **Rs.1,80,26,374/-** (Rupees One crore eighty lakh twenty-six thousand

three hundred and seventy-four only) which have been cleared and are not physically available, should not be held liable for **confiscation** under Section 111(d) of the Customs Act, 1962;

ii. Penalty should not be imposed upon M/s Primo International (India) under 112 (a) & Section 112 (b) of the Customs Act, 1962 for deliberate intention to circumvent the regulatory requirements mandated under the Medical Devices Rules 2017.

7. This Show Cause Notice is being issued under Section 124 of the Customs Act, 1962 without prejudice to any other action that may be taken against the Noticees or any other person / party connected with this case, under the Customs Act, 1962 or any other law for the time being in force. The aforesaid Noticees are directed to submit their reply in writing within 30 days of issuance of this notice. In their written reply, they should specifically mention whether they would like to be heard in person or through their authorized representative, by the adjudicating authority. They should also produce at the time of showing cause, all the evidences upon which they intend to rely in support of their defense. If no cause is shown against the action proposed in this Show Cause Notice within 30 days from the receipt of this Show Cause Notice (or extended period, if allowed) or if they or their representatives do not appear before the adjudicating authority as and when the case is posted for hearing, the case is liable to be decided ex-parte on the basis of facts and evidences available on record.

8. This Show Cause Notice is being issued on the basis of the evidences available on record. The Department reserves the right to add, alter, amend, modify or supplement this notice at any time on the basis of any evidence, material facts related to goods under investigation and any other import/smuggling by the said noticees, which may come to the notice of the Department after issuance of this notice and prior to the adjudication of the case.

9. The Copies of relied upon documents, as mentioned in the Show Cause Notice, are listed in **Annexure-R** and are enclosed with the Show Cause Notice and also are an integral part of this Show Cause Notice.

Digitally signed by Dipakbhai Zala
Date: 14-09-2026 15:54:33

(**Dipak Zala**)
Additional Commissioner of Customs,
Custom House, Mundra.

To,

M/s Primo International (India),
KH. NO. 16/9, First Floor, Gali No,
Burari Road, Swaroop Nagar,
North West Delhi - 110042

Copy to:

1. The Additional Director General, Directorate of Revenue Intelligence, Cochin Zonal Unit, Building No. 32/641 A, Vylopilli Road, St Thomas Lane, Palarivattom, Cochin – 682025.
2. The Deputy Director, O/o Directorate of Revenue Intelligence, Trivandrum Regional Unit, Krishnanjali, TC 12/741 (1) & (2), Kunnukuzhi, Varampassery Road, Vachiyoor Trivandrum- 695035.
3. The Deputy Commissioner, EDI, Customs Mundra (For uploading on Mundra Customs Website)
4. Office Copy.

Annexure-R

List of Relied Upon Documents

Sl. No.	Description of the Relied upon document/details (copies)
1	Letter dated 16.04.2025 bearing DIN -- 202504DDJ100005505F1 issued to M/s Primo International (India).
2	Email dated 14.05.2025 of Shri. Sahil Gupta, acknowledging the receipt of the letter dated 16.04.2025.
3	E-mail dated 27.05.2025 of M/s Primo International (India) submitting their import related documents to this office.
4	Summons CBIC-DIN-202511DDJ10000555CD9 dated 05.11.2025 issued to Shri. Sahil Gupta, Director, M/s Primo International (India), under Section 108 of the Customs Act, 1962.
5	Voluntary statement dated 05.11.2025, recorded from Shri. Sahil Gupta, M/s Primo International (India)under Section 108 of the Customs Act, 1962
6	Print-out of proof of registration of overseas suppliers with CDSCO.
7	Copy of BE No. 4191565 dated 26.06.2024, 5151672 dated 20.08.2024, and 8158905 dated 03.02.2025) wherein medical examination gloves declared under CTH 40151900 underwent Assistant Drug Controller (ADC) examination and were subsequently cleared by the proper officer.