



W.P.No.10929 of 2025

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IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED: 22.04.2025

CORAM :

THE HON'BLE MR.JUSTICE D.BHARATHA CHAKRAVARTHY

W.P.No.10929 of 2025
and W.M.P.No.12321 of 2025

Gillette India Limited
P And G Plaza, Cardinal Gracias Road,
Chakala, Andheri (East)
Mumbai 400 099, Maharashtra
Rep By Its Power Of Attorney, Shreya Mundra.
Vs.

.. Petitioner

1.Deputy Drugs Controller(I)
Central Drugs Standard Control Organisation,
(Medical Devices Division),
FDA Bhawan, Kotla Road, New Delhi- 110 002.

2.Deputy Drugs Controller (India)
Office Of The ADC (I) , CDSCO,
Seaport, Room No. 12, 13, 22 and 23
IV Floor, Annex Building, Rajaji Salai,
Custom House, Chennai-600 001.

3.Development Commissioner
SEZ Unit DTLs. IEC 0301035555,
Administrative Building, MEPZ Special Economic Zone,
GST Road, Tambaram, Chennai-45.



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4. Deputy Drugs Controller
Chennai Airport, Meenambakkam, Chennai, Tamil Nadu.

5. Venugopalan Nair
Deputy Commissioner Of Customs (Cco), Office Of The Chief Commissioner
Of Customs Chennai Customs Zone, Custom House, No.60, Rajaji Salai,
Chennai- 01.

.. **Respondents**

Prayer: Writ Petition filed under Article 226 of the Constitution of India seeking a Writ of Certiorarified Mandamus, to call for the records and quash the notice dated 04.03.2025 bearing file no. MED- 16012 (13)/ 3/ 2024- eoffice read with notice dated 08.10.2024, bearing File No.MED- 16012 (13) / 3/ 2024- eoffice, issued by the respondent no.1 to the petitioner, and further direct the respondent no.1 and respondent no.2 to issue a no -objection certificate forthwith to release the consignment imported under outward Bill of Entry bearing no. 5688249 dated 19.09.2024 and pass such further or other orders.

For the Petitioner : Mr.Thriyambak J.Kannan

For the Respondents : Mr.M.Ramamoorthy
Senior Panel Counsel for RR1 -4

ORDER

This Writ Petition is filed to call for the records relating to the impugned orders dated 04.03.2025 and 08.10.2024 and further to direct the respondents 1

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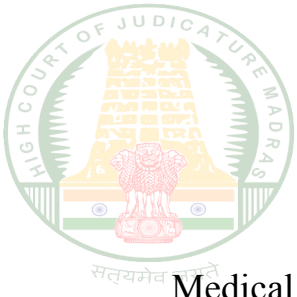
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and 2 to issue No Objection Certificate and forthwith release the consignment imported by the petitioner.

2. The case of the petitioner is that the petitioner during April – May 2024 placed orders and imported the consignment of Oral Dental Floss. The first consignment was received at the Chennai Port Trust on 07.07.2024 and the petitioner forwarded their inward bill of entry to the customs authority on 08.07.2024. Similarly, the second consignment was received on 26.07.2024 and the petitioners submitted their inward bill of entry bearing No.4736647 to the customs authority.

3. Upon the request of the petitioner, without clearing the goods, the customs authority issued a communication dated 08.10.2024, that is impugned in this Writ Petition, whereby it is stated that the authorities have examined the applications and they concluded that the Oral Dental Floss intended for removing food particles and plaque from the spaces between the teeth, may be classified as Clause A (non sterile non measuring) medical device under the



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Medical Device Rules, 2017, and therefore, they requested the petitioner to register the product under the said category in the MD online portal for its import and marketing in the Country. The learned counsel for the petitioner would submit that even from the counter, it can be seen that even now the notification that is being relied upon by the respondent is dated 06.01.2025, that is, after the inward entry of the goods. Secondly, he would submit that even the said notification is only a draft notification and as on date, there is no such classification finalised by the appropriate authority. Even today, an online application cannot be submitted as the drop down menu will not show the Oral Dental Floss in its menu.

4. Aggrieved by the same, the petitioner made further representation. The same is also now rejected by the second impugned order dated 04.03.2025, reiterating the same position and therefore, the petitioner is before this Court.

5. The Writ Petition is resisted by the respondent by filing a counter affidavit. Paragraph Nos.5 to 7 are extracted hereunder for ready reference:-



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“5. It is respectfully asserted that Dental Floss is classified as a Class A medical device, designed specifically for the removal of dental plaque from interproximal surfaces and to aid in the prevention of dental caries, thereby contributing to the maintenance of oral health and hygiene in accordance with relevant regulatory standards. It is hereby acknowledged that the product "Dental Floss" is categorized as a Class A medical device, which is non-sterile and non-measuring, as per the draft classification notice referenced under F. No. MED-16014(12)/1/2024-eoffice, dated January 6, 2025, and listed at serial number 188. The copy of Notice dated 06.01.2025 issued vide F. No. MED-16014(12)/1/2024-eoffice is annex herewith as ANNEXURE R-3.

6. It is respectfully submitted that as per notification G.S.R. 777(E) dated October 14, 2022, it is hereby acknowledged that Class A medical devices, specifically those that are non-sterile and non-measuring, are exempted from all provisions of Chapter IV, V, VII, VIII and XI certain provisions of the Medical Devices Rules, 2017. This exemption facilitates the regulatory framework governing the import and manufacture of such devices, thereby streamlining compliance requirements. However, it is imperative that the manufacturer or importer fulfills the obligation to register the aforementioned devices in accordance with the stipulations set forth in Chapter IIIB of the Medical Devices Rules, 2017. This registration is a prerequisite for availing the exemptions granted under the specified provisions.

7. It is further submitted that this office received a correspondence dated August 22, 2024, from the petitioner, indicating that they had imported a shipment of the product "Oral Dental Floss" in July 2024, which was pending customs clearance. The petitioner sought clarification regarding the classification of the aforementioned product as a medical device to facilitate its clearance from the customs authorities. In support of their inquiry, the petitioner provided a sample of the product's packaging label, along with a copy of a notice issued by this office under File No. 29/Misc./03/2020-DC (140) Part-5(a), which pertains to the classification of dental medical devices. In response to this request, this office issued a letter dated October 8, 2024, to the petitioner



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under reference F. No. MED-16012(13)/3/2024-eoffice, advising them to register the product as a Class A (non-sterile and non-measuring) medical device in accordance with the Medical Devices Rules, 2017. The copy of the letter dated 03.08.2024 and its reply dated 08.10.2024 is annex herewith as ANNEXURE R-4 (Colly).

It is further submitted that the petitioner submitted an appeal to this office via a letter dated October 9, 2024, contending that the product in question is not classified as a medical device in its country of origin and is not listed in the CDSCO classification list, thereby suggesting that it may not qualify as a medical device. Furthermore, the petitioner sought clarification regarding the regulatory pathway for the said product in a letter dated November 26, 2024, and subsequently requested a No Objection Certificate (NOC) for the clearance of the shipment of the product in a letter dated February 25, 2025. In response to these inquiries, this office issued a letter, reference F. No. MED-16012(13)/3/2024-eoffice, dated March 4, 2025, to the petitioner, M/s. Gillette India Ltd, instructing them to register the product "Oral Dental Floss" on the CDSCO Medical Devices online portal in order to comply with the labeling requirements necessary for the customs clearance of the withheld consignment. The copy of the letter dated 09.10.2024, 26.11.2024 & 25.02.2025 by petitioner and copy of its reply dated 04.03.2025 are annex herewith as ANNEXURE R-5 (Colly)."

6. *Mr.M.Ramamoorthy*, the learned Senior Panel Counsel would submit that once the goods are classified as medical devices, the petitioner has to register with reference to the same and there is no error whatsoever in the impugned orders.

7. I have considered the rival submissions made on either side and perused the material records of the case.

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8. Even as per paragraph No.5, which is extracted above, it can be seen that the notification, which is referred by the respondent itself reads as a draft classification notice. Therefore, when the notification is only in the draft stage, reliance placed by the respondent on the same is untenable. Secondly, the said notification was issued only on 06.01.2025, much later than the import of the goods by the petitioner in the month of May 2024. Therefore, the petitioner cannot be insisted upon to register the goods as medical devices.

9. Accordingly, this Writ Petition stands to be allowed, on the following terms:-

(i) The impugned orders dated 08.10.2024 and 04.03.2025 shall stand set aside;

(ii) The respondents 1, 2 and 4 shall issue No Objection Certificate and the goods of the petitioner shall be released forthwith;

(iii) The parties shall act upon the website uploaded copy of this order, without insisting for the certified copy;



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(iv) No costs. Consequently, the associated miscellaneous petition is closed.

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Neutral Citation : Yes/No

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To

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Central Drugs Standard Control Organisation,
(Medical Devices Division),
FDA Bhawan, Kotla Road, New Delhi- 110 002.

2. Deputy Drugs Controller (India)
Office Of The ADC (I) , CDSCO,
Seaport, Room No. 12, 13, 22 and 23
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