CUSTOMS, EXCISE & SERVICE TAX APPELLATE TRIBUNAL
NEW DELHI

PRINCIPAL BENCH - COURT NO. 1

CUSTOMS APPEAL NO. 55291 OF 2023

(Arising out of Order-in-Appeal No. CC(A) CUS/D-I/Import/NCH/6076/2022-23 dated 20.12.2022 passed by the Commissioner of Customs (Appeals), New Customs House, Near IGI Airport, New Delhi-110037)

M/s. Hemogenomics Pvt. Ltd., **.....Appellant**
B1, E27, Mohan Cooperative Industrial Area,
Mathura Road, New Delhi-110044

VERSUS

Commissioner of Customs (Appeal) **.....Respondent**
New Customs House,
Near IGI Airport, New Delhi-110037

APPEARANCE:

Shri Sandeep Chilana, Shri Priyojeet Chhatterjee, Shri Snehil Sharma and Shri Vindaya Agarwal, Advocates for the Appellant

Shri S.K. Rahman, Authorized Representative for the Department

CORAM: HON'BLE MR. JUSTICE DILIP GUPTA, PRESIDENT
HON'BLE MS. HEMAMBIKA R. PRIYA, MEMBER (TECHNICAL)

Date of Hearing: 13.02.2025
Date of Decision: 06.08.2025

FINAL ORDER NO. 51146/2025

JUSTICE DILIP GUPTA:

M/s. Hemogenomics Pvt. Ltd.[1] has sought the quashing of the order dated 20.12.2022 passed by the Commissioner of Customs (Appeals), New Delhi[2] by which the appeal filed by the appellant against the order dated 18.10.2021 passed by the Assistant Commissioner has been dismissed and the order of the Assistant Commissioner has been upheld. The Assistant Commissioner, by the order dated 18.10.2021, held that Procleix Ultrio Plus Assay Kits and Procleix Ultrio Elite Assay Kits[3] and their reagents imported

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1. **the appellant**
2. **the Commissioner (Appeals)**
3. **the imported test kits**

by the appellant are classifiable under Customs Tariff Item[4] 3822 00 90 of the Customs Tariff Act, 1975[5] and would not be eligible for benefit of Notification No. 50/2017-Cus dated 30.06.2017[6] and Notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017[7].

2. The appellant claims to be engaged in the business of import and supplies of the imported test kits and reagents which are supplied to medical institutions like AIIMS Delhi, AIIMS Rishikesh, CMC Vellore, PGI Chandigarh and Sri Gangaram Hospital in India. The appellant has been importing these imported test kits from its foreign supplier M/s Grifols (HK) Limited. The imported test kits are used at hospitals and blood banks for screening of blood for the purpose of detecting HIV and Hepatitis.

3. The appellant cleared the imported test kits by claiming benefit of 'Nil' Basic Customs Duty[8] and 5% IGST. According to the appellant, the imported test kits are eligible for exemption from BCD under Serial No. 167(A) of the Exemption Notification and concessional rate of 5% IGST under Serial No. 180 of Schedule I to the IGST Rate Notification.

4. The relevant portion of the Exemption Notification dealing with BCD and IGST is reproduced below:

> "**Notification: 50/2017-Cus. Dated 30-Jun-2017**
>
> ****** **the Central Government,** on being satisfied that it is necessary in the public interest so to do, **hereby exempts the goods of** the description specified in column (3) of the Table below or column (3) of the said Table read with the relevant List appended hereto, as the case may be, and falling within the Chapter, heading, sub-heading or tariff item of the First Schedule to the said Customs Tariff Act, as are specified in the

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4. CTI
5. the Tariff Act
6. the Exemption Notification
7. the IGST Rate Notification
8. BCD

corresponding entry in column (2) of the said Table, when imported into India, -

(a) **from so much of the duty of customs leviable** thereon under the said First Schedule as is in excess of the amount calculated at the standard rate specified in the corresponding entry in column (4) of the said Table; and

(b) **from so much of integrated tax leviable** thereon under sub-section (7) of section 3 of said Customs Tariff Act, read with section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017) as is in excess of the amount calculated at the rate specified in the corresponding entry in column (5) of the said Table,

subject to any of the conditions, specified in the Annexure to this notification, the condition number of which is mentioned in the corresponding entry in column (6) of the said Table :

S. No.	Chapter or Heading or sub-heading or tariff item	Description of goods	Standard rate	Integrated Goods and Services Tax	Condition No.
(1)	(2)	(3)	(4)	(5)	(6)
167.	28,29,30 or **38**	**The following goods namely:-**			
		(A) Lifesaving drugs/medicines including their salts and esters/**and diagnostic test kits specirfied in List 4.**	Nil	-	-
		(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)	Nil	-	9
		(C) Other life saving drugs or medicines	Nil	-	16

(emphasis supplied)

6. The relevant portion of List 4 is reproduced below:

"**List 4**

(28) Diagnostic kits for detection of HIV antibodies"

7. The relevant portion of IGST Rate Notification dated 28.06.2017 is reproduced below:

"**Notification: 1/2017-Integrated Tax (Rate) dated 28-Jun-2017**

Rate of IGST on specified goods- Schedule I to VI

In exercise of the powers conferred by sub-section (1) of section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017), **the Central Government,** on the recommendations of the Council, **hereby notifies the rate of the integrated tax of-**

(i) 5 per cent in respect of goods specified in Schedule I

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appended to this notification (hereinafter referred to as the said schedules), that shall be levied on inter-State supplies of goods, the description of which is specified in the corresponding entry in column (3) of the said Schedules, falling under the tariff item, sub-heading, heading or Chapter, as the case may be, as specified in the corresponding entry in column (2) of the said Schedules.

Schedule 1-5%

S.No.	**Chapter/Heading/Sub-heading/ Tariff item**	**Description of Goods**
(1)	(2)	(3)
180.	30 or any chapter	Drugs or medicines including their salts and esters and **diagnostic test kits, specified in List 1 appended to this Schedule**

8. The relevant portion of List I referred to above is reproduced below:

"**List 1[See S. No. 180 of the Schedule I]**

(150) Diagnostic Kits for detection of HIV antibodies."

5. The dispute in the present appeal relates to 6 Bills of Entry which were filed by the appellant between 13.07.2021 and 20.07.2021.

6. The department disputed the eligibility of the appellant to claim the benefit of the aforesaid Exemption Notification and the appellant deposited 100% of the disputed differential duty (BCD @ 30% and IGST @12%) under protest. Later, based on legal advice, the appellant during the investigation believed that the imported test kits would be classifiable under CTI 3822 00 19. According to appellant, the department refused to allow the appellant to re-classify the product under CTI 3822 00 19 as against CTI 3822 00 90 which the appellant had adopted earlier.

7. The adjudicating authority took up the matter for passing re-assessment order under section 17(5) of the Customs Act, 1962[9] and framed the following questions:

> "A. Whether the impugned goods are classifiable under CTH 38220019 as contended by the importer;
>
> B. Whether the impugned goods are eligible for exemption provided to 'Diagnostic Kits for Detection of HIV Antibodies' under S. no. 167 (A) of notification no. 50/2017-customs dated 30.06.2017 as well as under IGST Notification No. 01/2017 dated 28.06.2017."

8. The adjudicating authority the held that test kits imported by the appellant under the 6 Bills of Entry filed in the month of July, 2021 are appropriately classifiable under CTI 3822 00 90 and would not be eligible for benefit of the Exemption Notification and the reduced rate @5% IGST Rate Notification. The relevant portion of the order dated 18.10.2021 is reproduced below:

> "**27.** In the light of the above discussions, I conclude that:-
>
> i. **The impugned Kits are qualitative in-vitro nucleic acid amplification test to detect**

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9. the Customs Act

HIV-I RNA, HCV RNA and HBV DNA in plasma and serum specimen from individual human donor and are not for medical diagnosis of HIV infection in a patient. The impugned Kits do not detect antibodies of HIV.

ii. **These Assays are not used for medical diagnosis purposes.** The manufacturer of the impugned goods has clearly mentioned in the intended use that the goods are not an aid in diagnosis of infection with HIV, HCV or HBV.

iii. **Detection of HIV Antibodies can be done by tests such as Enzyme linked immunosorbent Assays** (ELISAs), Rapid Tests, Western Blots, Chemiluminescence Immunoassays (CIA), ImmunoFloresent Assays and Line Immunoassays. **The impugned Kits do not fall under any of these categories of tests. These Kits are nucleic acid amplification (NAT) test and are not meant for detecting HIV Antibodies.**

iv. **The impugned test Kits are not classified as test for detection of HIV Antibodies by National AIDS Control Organisation, Ministry of Health and Family Welfare (NACO).**"

(emphasis supplied)

9. Feeling aggrieved, the appellant filed an appeal before the Commissioner (Appeals) and as noted above, the appeal was dismissed and the order dated 18.10.2021 passed by the Assistant Commissioner was upheld. The relevant portions of the order passed by the Commissioner (Appeals) are reproduced below:

"**5.2 The issues to be decided are: whether the Adjudicating Authority was correct in rejecting the claim of the Appellant that the impugned goods being medical diagnosis devices are classifiable under CTH 38220019**

and holding that these are not used for medical diagnosis purposes therefore classifiable under CTH 38220090; and whether BCD exemption was admissible under the notifications 050/2017-Cus dated 30.06.2017, S. No. 167(A), (List 4, S. No.28) and IGST exemption S. No. 180 of IGST Schedule-I of notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017 (List 1, S. No. 150) for import of the impugned goods.

5.3 The Appellant has claiming that impugned goods are used for the following purposes:

a) Screening of human immunodeficiency ('HIV'), Hepatitis B virus ('HBV'), and Hepatitis C virus ('HCV') in the blood of the donors;

b) Detection of HIV/HBV/HCV and

c) Confirming HIV/HBV/HCV antibody diagnosis

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5.5 On going through these submissions, I find that the intended uses mentioned in Form-5 of the Import License of the impugned goods are as under:

> "The Procleix Ultrio Elite Assay is a qualitative in vitro nucleic acid amplification test for the detection of human immunodeficiency virus type 1 and human immunodeficiency virus test 2 (HIV) RNA, hepatitis C virus (HCV) RNA, and/or donors, tested individually or in pools. It is also intended for use in testing plasma and serum to screen organ and tissue donors, including cadaveric (nonheart-beating) donors".

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5.8 From the above, it is clear that the intended use section in the PI of the Products enumerate all uses for which the products have approval. Other purposes for which the product might be used but the competent authority has denied the use are clearly written as "……is not intended for use ……." From the PI of the impugned goods available on the website of the US FDA, it is very clear that these do not have approval for use as diagnostic kit of HIV.

Thus, additional use of the impugned goods as a diagnosis kit does not have approval of the competent authority.

5.9 ***** Thus, out of the several testimonials submitted by the Appellant, only the testimonial issued by Sir Ganga Ram Hospital says that in addition to intended use of the impugned goods use they also use these as the diagnostic kit for the HIV i.e., for the use which has not been approved by the competent authority. **Focusing only on the use enumerated in the testimonials submitted by the Appellant, it is evident that their most of the customers use the impugned goods only for screening the presence of HIV-1, HIV-2, HCV or HBV and not as a diagnostic kit for the HIV.**

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5.16 The Appellant had claimed that they are entitled for BCD exemption benefit under notifications 050/2017-Cus dated 30.06.2017, S. No. 167(A), (List 4, S. No. 28) and S. No. 180 of IGST Schedule-I of notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017 (List 1, S. No. 150). Before proceeding further, it would be helpful to reproduce the relevant portion of the said Notifications, which is as under: - *****

5.17 From the above it is clear BCD exemption under Sr. No. 167 of the Notification No. 50/2017 under 'life saving diagnostic test kits' is available to the import of 'diagnostic kits for detection of HIV antibodies' only. In the 'National Guidelines for HIV Testing' published by National AIDS Control Organization (NAACO), Government of India in 2015, Serological Tests and Nucleic Acid Amplification Test (NAAT) has been discussed as two distinct category of diagnosis test of HIV. Thus, BCD exemption under the Notification admissible only for the import of "Diagnostic kits for detection of HIV antibodies" i.e. a class of diagnosis kit under Serological Tests cannot be claimed for the

import of a diagnostic kit based on NAAT i.e., distinct from the Serological Test. Thus, the impugned goods based on NAAT technique, irrespective of their use in diagnosis of HIV; don't qualify for the BCD exemption under Sr. No. 167 of the Notification No. 50/2017.

5.18 Relevant portion of the Notification No. 1/2017-Integrated Tax (Rate), Dated 28th June, 2017 is reproduced below: *****

5.19 Firstly, from the above, it is clear that the Sr. No. 180 of the Schedule-I covers some of the specified goods of Chapter 30 only, as the classification issue of the impugned goods is confined to the Chapter 38 only, therefore lower IGST rates @5%, admissible to the goods failing under No. 180 of Schedule-1 cannot be claimed for the impugned goods, which have been classified under Chapter 38.

5.20 In view of the above discussions and findings the appeal has no merits. Accordingly, I pass the following order."

(emphasis supplied)

10. According to the appellant, the imported test kits are multiplex diagnostic kits used for the following purposes:

(a) Screening of human immunodeficiency virus ('HIV'), Hepatitis B virus ('HBV'), and Hepatitis C virus ('HCV') in the blood of the donors;

(b) Detection of HIV/HBV/HCV; and

(c) Confirming HIV/HBV/HCV antibody diagnosis.

11. The appellant further states that two-step process involved in using the imported test kits. These two-step process are as follows:

First step: Specimens collected are tested for screening the presence of any of the viruses i.e., HIV, HBV or HCV with the help of multiplex (combo) assay. Test result

shows 'reactive' against the specimen if there is presence of any of the three viruses. If specimen is free of all the three viruses test result shown is 'non-reactive'.

Second step: Specimens for which the test result is 'reactive' in the first step, are then further tested for the presence of three viruses separately with the help of discriminatory assay. The discriminatory assay reagent uses separate probe reagent specific for HIV, HCV and HBV instead of multiplex probe used in the initial test. Discriminatory test detects the presence of HIV, HCV and HBV separately. It is pertinent to note that multiplex (combo) assay and discriminatory assay are part of the same product i.e. Procleix Ultrio Kits but are employed differently in the second step.

12. After the second step of testing, if any specimen is detected with any of the viruses (HIV, HCV, or HBV), the diagnose or assessed person from whom such specimen has been collected is informed and referred for further treatment. In this regard, 'Guidelines for blood donor selection and blood donor referral' issued by National Aids Control Organization[10], Ministry of Health and Family Welfare - Government of India, also mandates that all donors detected with HIV are referred to integrated Counseling and Testing Center[11].

13. The appellant further claims that the imported test kits are a multiplex (combo) assay; hence it is cheaper, faster and convenient to screen for HIV, HCV and HBV together so that infected specimens are discarded and are not transfused. Further, only positive cases are sent for discriminatory testing

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10. NACO
11. ICTC

where particular virus is detected and concerned person is referred for further treatment or test. Since, Ultrio Elite test detects the viruses, it is also used by hospitals to confirm the antibody test results. Procleix Ultrio test kits are also sometimes also used by the hospitals and laboratories to screen for the viruses for dialysis patients, organ transplant patients and other vulnerable patients before the surgery.

14. Thus, according to the appellant, the imported test kits are of utmost public importance as the same ensure timely screening of blood at various government and private hospitals.

15. Shri Sandeep Chilana, learned counsel for the appellant assisted by Shri Priyojeet Chhatterjee, Shri Snehil Sharma and Shri Vindaya Agarwal made the following submissions:

(i) The appellant is entitled to the benefit of the Exemption Notification and the IGST Rate Notification as the imported test kits are "diagnostic test kits" and are used for detection of HIV antibodies;

(ii) The Exemption Notification and the IGST Rate Notification do not in any manner refer to the technology used behind such diagnostic kits like Sero Logical Test or Nucleic Acid Amplification Test[12];

(iii) The allegation of the department that the diagnostic imported test kits are not capable of detecting HIV antibody but HIV virus is not correct as the letter submitted by the appellant from various reputed hospitals confirms that the diagnostic kits are used for screening of blood to confirm not only virus but also confirm HIV antibodies in various environment;

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12. NAAT

(iv) The conclusion arrived at by the Commissioner (Appeals) that the diagnostic kits are incapable of confirming HIV antibody, without any technical analysis or expert opinion, is not correct;

(v) In 1981, when exemption was granted to diagnostic kits for screening of HIV antibody no technology existed which could confirm the presence of virus and only antibodies could be confirmed. However, with the advancement of technology sometimes after 2001 NAAT technology based testing kits were developed for screening of blood for detection and confirmation of HIV virus. Advancement made in the scientific field to bring out a new innovation would not mean that the benefit of the Exemption Notification and the IGST Rate Notification would be denied to the appellant;

(vi) The appellant under a mistaken bona fide belief classified the products under CTI 3822 00 90. However, when the investigation was initiated, the appellant made an effort to change the classification to CTI 3822 00 19;

(vii) The Commissioner (Appeals) has incorrectly relied on the Import License and contents of the Package Insert[13] to conclude that the imported test kits are not intended for use as an aid in diagnosis of infection with HIV-I, HIV-II, HCV or HBV without considering the meaning and scope or the word "medical diagnosis" in the Chapter Heading;

(viii) The Commissioner (Appeals) failed to appreciate the technical evidence produced by the appellant that use of such kits in blood banks and hospitals for screening and detection would qualify as "medical diagnosis" as contemplated under the Exemption Notification;

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13. PI

(ix) It is well settled proposition of law that the onus to impose a particular classification rests with the department; and

(x) The benevolent Exemption Notifications achieves larger public good and has, therefore, to be interpreted liberally keeping in mind the advancement of technology.

16. Shri S.K. Rahman, learned authorized representative appearing for the department, however, supported the impugned order passed by the Commissioner (Appeals) and made the following submissions:

(i) The imported test kits are not for detection of HIV antibodies and, therefore, would not be entitled to the benefit of the Exemption Notification and the IGST Rate Notification as they confer benefit only to diagnostic kits for detection of HIV antibodies;

(ii) The Exemption Notification and the IGST Rate Notification have to be interpreted strictly;

(iii) The imported test kits are used for testing of viruses i.e. nucleic acid test and not for detection of antibodies. The imported test kits are correctly classifiable under CTI 3822 00 90; and

(iv) The imported test kits are not for life-saving diagnostic use;

17. The submissions advanced by the learned counsel for the appellant and the learned authorized representative appearing for the department have been considered.

18. The first issue that arises for consideration is whether the imported test kits imported by the appellant can be denied exemption from BCD and lower rate IGST merely because such exemption is restricted only to diagnostic kits for “detection of HIV antibodies” and not for detection of HIV nucleic acid by NAAT.

19. To appreciate this issue, it would be necessary to examine the history of HIV epidemic. The HIV epidemic in India began in 1986-1987 following detection of the first HIV. Testing is integral to HIV prevention, treatment and care. Thus, knowledge of HIV status is important for preventing spread of disease. The appellant has elaborately described the aforesaid in the following manner:

(i) HIV is a lentivirus that infects and destroys cells in the immune system. There are two HIV types, HIV-1 and HIV-2. HIV-1 is the most prevalent type throughout the world. Early knowledge of HIV status is critical for linkage to medical care and treatment so that it can reduce mortality and improve quality of life. It is this critical clinical encounter that serves as the starting point for diagnosing and treating persons who are infected and delivering preventive services to those who are uninfected. **HIV diagnosis is made by either demonstrating the presence of virus or viral products in the host or alternatively by detecting host response to the virus**;

(ii) **Thus, over a period, different technologies have evolved with respect to HIV testing, as per which HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies; or by Nucleic Acid Amplification Test (NAAT) to detect HIV nucleic acids as explained below:**

(a) **<u>Serological Tests</u>: HIV antibody tests only look for antibodies to HIV in blood or oral fluid.** Enzyme linked immunosorbent assays (ELISAs), rapid tests and western blots (WBs) are the common tests for detecting HIV antibodies.

Antibody tests can usually take 23 to 90 days to detect HIV infection after an exposure.

A combination of both antigen and antibody test looks for both HIV antibodies and antigens. Antibodies are produced by immune system when one is exposed to viruses like HIV. Antigens are foreign substances that cause immune system to activate. If one has HIV, an antigen called p24 is produced even before antibodies develop. **An antigen/antibody test performed on blood can usually detect HIV infection 18 to 45 days after an exposure.**

(b) <u>Molecular Tests:</u> These are sensitive tests for diagnosis of HIV infections on the basis of PCR (polymerase chain reaction) **or NASBA** (nucleic acid sequence-based amplification). **These tests look for the actual virus in the blood and involves drawing blood from a vein. The test can either tell if a person has HIV or tell how much virus is present in the blood (known as an HIV viral load test). A nucleic acid test (NAT) can usually detect HIV infection within 10 to 33 days after an exposure.** They use polymerase chain reactions (PCRs) or reverse transcription-polymerase chain reaction (RT-PCR) for the detecting various HIV structural genes. **These are test of choice in certain situations, such as early infant diagnosis and during window period. Diagnosis in a child less than 18 months cannot be done using antibody-based assays as maternal antibodies may be present in the infant's circulation. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be reliably made by DNA/RNA PCR.**

(iii) Substantive and significant advances have been made in the last two decades in the characterization of human immunodeficiency virus (HIV) infections using molecular techniques. These advances include the use of real-time measurements, isothermal amplification, the inclusion of internal quality assurance protocols, device miniaturization and the automation of specimen processing. The result has been a significant increase in the availability of results to a high level of accuracy and quality. Molecular assays are currently widely used for diagnostics, antiretroviral monitoring and drug resistance characterization in developed countries.

20. It would also be useful to consider customs duty exemptions offered to life-saving drugs, medicines or equipment including HIV-test kits. As regard HIV test kits, the entry relating to "Diagnostic kits for detection of HIV antibodies" was added to the list of life-saving drugs or medicines in 1989 when HIV cases started increasing and attracted attention, both nationally and internationally. A tabular summary of Customs duty exemptions awarded to "life-saving drugs, medicines or equipment" including "HIV test kits" is contained in the following Chart:

S.N.	**Year**	**Notification Number**	**Relevant Entry**	**Description of list covering HIV kits**
1.	1981	Notification No. 208/81-Cus. dated 22.09.1981	Life-saving drugs or medicines	-
2.	**1989**	**Notification No. 209/89-Cus. dated 17.07.1989**	**Life-saving drugs or medicines**	**218. Diagnostic kits for detection of HIV antibodies**
3.	**1995 till date**	Various notifications	Life Saving drugs or medicines including diagnostic test Kits	Specific List Number under different notifications included Diagnostic kits for detection of HIV antibodies.

21. Having considered the aforesaid facts, it would be appropriate to examine the case of the appellant.

22. An Import License dated 12.05.2020 was issued to the appellant for the brand name "Procleix Ultrio Elite" and the Generic Name "Procleix Ultrio Elite Assay Kit (A qualitative-In-Vitro nucleic acid amplification test for the detection of HIV 1 & 2 RNA, HCV RNA and HBV DNA in plasma and serum specimens from human donors)" under the provisions of the Medical Device Rules 2017.

23. Form MD-15 deals with License to Import Medical Device. The relevant portion of the Form is reproduced below:

FORM MD-15
[See sub-rule (1) of rule 36]
Licence to Import Medical Device

Licence No.: IMP/IVD/2020/000479

1. M/s Hemogenomics Private Limited, No. 26, 3rd Floor, ITI Layout New BEL Road, Mathikeri, Bangalore, Bengaluru (Bangalore) Urban, Karnataka (India) – 560054 Telephone No.: 08042151017 FAX: 08040925711 is hereby licenced to import the medical device(s) manufactured by overseas manufacturer having manufacturing site as specified below.

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3. Details of medical device(s):

S.No.	Medical Device Details
1	**1. Generic Name: Procleix Ultrio Elite Assay Kit (A qualitative-In-Vitro nucleic acid amplification test for the detection of HIV 1 & 2 RNA, HCV RNA and HBV DNA in plasma and serum specimens from human donors)** 2. Brand Name(if registered under the Trade Marks Act, 1999): Procleix Ultrio Elite 3. Class of Medical Device: Class D 4. Shell Life: 24 months 5. Sterile/ Non-sterile: Non-Sterilized **6. Intended Use: The Procleix Ultrio Elite Assay is a qualitative in vitro**

	nucleic acid amplification test for the detection of human immunodeficiency virus type 1 and human immunodeficiency virus type 2 (HIV) RNA, hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA in plasma and serum specimens from human donors, tested individually or in pools. It is also intended for use in testing plasma and serum to screen organ and tissue donors, including cadaveric (nonheart-beating) donors. 7. Material of Construction: NA 8. Dimension: NA 9. Model No.: NA

(emphasis supplied)

24. It would also be useful to refer to the Package Insert of Procleix Ultrio Elite and the relevant portion is reproduced below:

> "**Intended Use**
>
> **The Procleix® Ultrio Elite Assay is a qualitative in vitro nucleic acid amplification test to screen for human immunodeficiency virus type 1 (HIV-1)**, hepatitis C virus (HCV) RNA hepatitis B virus (HBV) DNA and detect human immunodeficiency virus type 2 (HIV-2) RNA **in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, and source plasma, and from other living donors.** It is also intended for use in testing plasma and serum to screen organ and tissue donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens from cadaveric (non-heart-beating) donors.
>
> This assay is not intended for use on cord blood specimens.
>
> It is also intended for use in testing pools of human plasma and pools of human serum composed of equal aliquots of not more than 16 individual specimens from donors of whole blood, blood components, hematopoietic stem/progenitor cells sourced from bone marrow, peripheral blood or cord blood, and from donors of donor lymphocytes for infusion. It is also intended for use in testing pools of

human plasma composed of equal aliquots of not more than 96 individual donations from donors of source plasma.

This assay is intended to be used in conjunction with licensed tests for detecting antibodies to HIV-1, HIV-2, HCV, and hepatitis B core antigen, and with licensed tests for hepatitis B surface antigen (HBsAg).

This assay is not intended for use as an aid in diagnosis of infection with HIV-1, HIV-2, HCV or HBV.

The Procleix® Ultrio Elite Assay can be considered a supplemental test that confirms HIV infection for specimens that are repeatedly reactive on a licensed donor screening test for antibodies to HIV, and reactive on both the Procleix® Ultrio Elite Assay and on the Procleix® Ultrio Elite HIV Discriminatory Assay."

(emphasis supplied)

25. It would also be useful to examine the National Guidelines for HIV Testing containing information regarding different types of tests for HIV published in July, 2015.

26. The relevant portions of the Guidelines contained in Chapter I are reproduced below:

"**Diagnosis of HIV Infection**

Like other infectious diseases, HIV diagnosis is made by either demonstrating the presence of virus or viral products in the host, alternatively by detecting host response to the virus. An HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies or by Nucleic Acid Amplification Test (NAAT) to detect HIV nucleic acids.

Serological Tests: Enzyme linked immunosorbent assays (ELISAs), rapid tests and western blots (WBs) are the common tests for detecting HIV antibodies. To accurately diagnose an HIV infection, these tests are used in a

specific sequence or algorithm. Additionally, Chemiluminescence Immunoassays (CIA), Immuno Floresent Assays and Line Immunoassays are also available for specific HIV antibody detection. Commercial assays are also available for P24 antigen detection.

NAAT: These are sensitive tests for diagnosis of HIV infections. They use polymerase chain reactions (PCRs) for the detecting various HIV structural genes (usually gag, pol and env). PCRs are the test of choice in certain situations, such as early infant diagnosis and during window period. Branch DNA (bDNA) assays based on signal amplifications are also used.

Diagnosis in a child less than 18 months cannot be done using antibody based assays as maternal antibodies may be present in the infant's circulation. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be made by DNA PCR."

(emphasis supplied)

27. Chapter 3 of the Guidelines deals with Serological Diagnosis of HIV Infection and the portions dealing with Limitations of Antibody Assays is reproduced below:

"**Limitations of Antibody Assays**

Antibodies are not detectable in the window period. Therefore, antibody detection tests are of no use during this period. Diagnostic tests based on antibody detection are also not useful in the diagnosis of infection in children below 18 months of age. Babies born to HIV positive mothers may have passively acquired maternal antibodies. **In this situation, tests that detect the viral genome may be done for early diagnosis (see Chapter4).** NACO is now promoting the use of the DBS technique for early infant diagnosis, based on the detection of HIV 1 DNA viral nucleic acid. The test is discussed in detail in chapter four."

(emphasis supplied)

28. Chapter 4 of the Guidelines deal with Molecular and Other Assays for the Diagnosis of HIV Infection and the relevant portion is reproduced below:

> "**Introduction**
>
> Serological assays for the diagnosis of HIV infections. In certain situations, such as patients in the window period and infants born to HIV positive mothers antibody detection assays cannot be relied upon. In these situations, the diagnosis of HIV infections is established using molecular assays to detect viral genomes. **This chapter describes molecular assays, assays for virus isolation, and detection of virus core proteins (p24).**
>
> **Diagnosis of Paediatric HIV Infection (<18 months)**
> **The standard diagnostic method for HIV infection in adults (i.e., testing for antibodies) has limited utility in newborns, infants, and children less than 18 months of age.** This is due to the transplacental transfer of maternal IgG (including HIV-specific antibodies) from infected mothers to their babies during pregnancy. **HIV antibody tests are reactive in most infants born to HIV positive mothers, though the infection is transmitted to less than half of such infants (even in the absence of ART). HIV antibodies may persist in an infant's blood until 18 months after birth, and are difficult to differentiate from those produced by an infected infant. Therefore, antibody tests cannot produce a definitive diagnosis of HIV infection until 18 months of age. Waiting until this time delays specific treatment. In this situation, Nucleic Acid Testing (NAT) can facilitate early infant diagnosis. NACO recommends the use of a qualitative HIV-1 DNA PCR.**

> Further Reading: Laboratory Guidelines for HIV Diagnosis in infants and children<18 months, NACO 2010
>
> **Detection of Acute HIV Infection**
>
> **Virological tests can be used for the detection of acute HIV infection during the "window period," before HIV antibodies become detectable. Though positive NAT results confirm the HIV diagnosis, the NAT result may turn out negative if tested within 7 to 10 days of exposure. NAT tests may be successfully employed for the detection of HIV infection if appropriate infrastructure and technical expertise is available.** At present, NACO does not recommend the use of NAT for the diagnosis of acute HIV infection.
>
> NATs include tests for the qualitative detection of HIV-1 DNA or RNA, as well as the quantitative detection of HIV-1 RNA (viral load determination) through various assays."
>
> **(emphasis supplied)**

29. What transpires from the aforesaid is that there are two types of HIV out of which HIV-1 is most prevalent and early knowledge of HIV status is critical for medical care and treatment. The first HIV antibody test was developed in 1985. HIV antibody test only look for antibodies to HIV in blood or oral flood. HIV infection is detected after an exposure between 23-90 days. With passage of time, HIV testing improved and on account of technological advancements different types of test methods have also evolved. These tests have not only reduced the detection window period considerably, but have also enabled ascertainment of virus load to determine whether the patient has an acute infection. These tests detect HIV infection even before HIV antibodies become detectable.

30. Thus, over a period of time, different technologies have evolved with respect to HIV testing. HIV diagnosis is commonly made through serological assays to detect HIV specific antibodies. On the other hand, NAAT looks for actual virus in the blood. This test can not only determine whether a person has HIV but can also determine how much virus is present in the blood. Diagnosis in a child less than 18 months cannot be done by using antibody assays. Therefore, up to the age of 18 months, the diagnosis of HIV infection can only be done by NAAT test. Further, mere detection of HIV is not enough for treatment of HIV infection in a body. It is equally important to continuously monitor the spread of HIV infection in the body for determining the course of treatment. It is for this reason that the use of immunologic tests and virological tests have assumed importance. These kits not only detect the presence of HIV infection, but being more sensitive and accurate, are used for regular monitoring of the spread of HIV infection in the body. Thus, these kits are required for identifying the course of treatment of HIV and thereby fighting the epidemic of HIV, which is the sole intention behind introducing the exemption benefit to life-saving drugs/medicines and diagnostic kits for HIV.

31. As noted above, the Exemtion Notification dated 30.06.2017 exempted duty of customs and integrated tax to diagnostic tests and kits specified in List 4, which list again referred to diagnostic kits for detection of HIV antibodies. The IGST Rate Notification dated 28.06.2017 also exempted diagnostic test kits specified in List 1, which list referred to "diagnostic kits for detection of HIV antibodies". The diagnostic kits that were imported by the appellant were sold under a trade name Procleix Ultrio Plus Assay Kits and Procleix Ultrio Elite Assay Kits and are called "Procleix Ultrio Elite Assay Kit (A qualitative-In-Vitro nucleic acid amplification test for the detection of

HIV 1 & 2 RNA, HCV RNA and HBV DNA in plasma and serum specimens from human donors) test kits. The reason why exemption has not been granted to the appellant by the impugned order is that these test kits are not diagnostic kits for detection of HIV antibodies.

32. The contention of the learned counsel appearing for the appellant is that the Exemption Notification under consideration in this appeal should be widely construed to cover diagnostic kits imported by the appellant, which kits provide an essential diagnostic tool for detection and prognosis of HIV. The contention, therefore, is that there is no rationale for exclusion of this diagnostic kit when the kits for detectable antibodies are included. Learned counsel for the appellant, therefore, submitted that the said entry should be interpreted in a broad manner to include kits working on technologically advanced methodology. Learned counsel also submitted that technical progress and development must not be overlooked and the new products/innovations serving the same objective should be considered as part and parcel of the same entry. To support this contention, learned counsel placed reliance upon the following decisions:

(a) **Collector of Customs & Central Ex.** vs. **Lekhraj Jessumal & Sons**[14]; and

(b) **Collector of Customs, New Delhi** vs. **Ethnor Ltd.**[15]

33. Learned authorized representative appearing for the department, however, submitted that the exemption under Exemption Notification is restricted only to diagnostic kits for "detection of HIV antibodies". Such an exemption has to be interpreted strictly and technological advancements cannot be considered unless the Notification is suitably amended. Learned authorized representative, therefore, submitted that when various methods

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14. 1996(82) E.L.T. 162 (S.C.)
15. 1996 (86) E.L.T. 558 (Tribunal)

of detecting HIV are present, it is only the method of detection of HIV antibodies that has been exempted and no other method has been exempted.

34. As noticed above, the first HIV antibody test was developed in 1985. Since then, on account of technological breakthroughs, different types of testing methods have evolved over a period of time and the subsequent generation tests have not only reduced the detection window period considerably, but have also enabled ascertainment of virus load to determine whether the patient has an acute infection. Earlier, HIV diagnosis was made through serological tests only to detect HIV specific antibodies, but these HIV antibody tests only look for antibodies and it takes about 23-90 days to detect HIV infection after an exposure. On the other hand, molecular tests look for the actual virus in the blood and the test can tell whether a person has HIV and if so, how much virus is present in the blood. Such tests can have a very reduced window period for detecting of HIV infection. The antibodies tests, therefore, have inherent limitations. The antibodies are not detectable up to a certain window period and they cannot also diagnose infection in children below 18 months of age. Nucleic Acid Amplification Test, however, can be used for the detection of acute HIV infection during a much lesser window period even before HIV antibodies become detectable. This test includes qualitative detection of HIV as well as quantitative detection of HIV (viral load determination). This test can also diagnose HIV in children below the age of 18 months. It is not that the test based on advanced technology has replaced the antibody test. Both the tests can be undertaken.

35. It is correct that the Exemption Notification dated 30.06.2017 at Serial No. 167 refers to diagnostic test kits specified in List 4 and List 4 mentions

"diagnostic kits for detection of HIV antibodies", but the issue that arises for consideration is whether this entry should be interpreted in a restricted sense or in a broad manner so as to include kits working on technologically advanced methodology.

36. This issue was examined by the Supreme Court in **Lekhraj Jessumal**. Lekhraj Juessmal had imported miniaturized switches for use in electronic hearing aids which it manufactured. The two types of switches were the conventional one called water switches and the newly innovated, reed switches. The appellant imported reed switches. The department believed that reed switches were not entitled to concessional rate of import duty. The contention of the department was that the words **'**switches, miniaturized**'** as component parts of hearing aid should be understood to mean only those types of switches which were generally used in the manufacture of hearing aids at the time of publication of the import policy. This understanding of the department was not accepted by the Supreme Court and the relevant paragraphs of the judgment are reproduced below:

> "**2.** The respondent had imported miniaturised switches for use in electronic hearing aids which it manufactured. It appears that there are two types of such switches, the conventional one then being wafer switches and the other, newly innovated, being reed switches. It was the latter type of switch which was imported. The Customs authorities took the view that the respondents' import licence did not cover reed switches and they were not entitled to the concessional rate of import duty. The stand of the Customs authorities was, ultimately, assailed in the writ petition filed by the respondent before the High Court. The Writ petition was allowed. An appeal was preferred and it is the judgment in appeal which is under challenge before us.
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> **3.** The High Court in the impugned order noted that the stand of the Customs authorities was that the

words "switches, miniaturised" as component parts of hearing aids should be understood to mean only those types of switches which were generally used in the manufacture of hearing aids at the time of publication of the Import Policy for the relevant year, namely 1977, and that these words could not be said to include any other type of switch even if such other type of switch could be used in the manufacture of hearing aids. **The Division Bench observed, in our view, very rightly, that such an interpretation overlooked that industry was not static and that there was continuous technical progress therein. New processes and new methods developed from time to time and new material and components or types of components superseded others. It was unreasonable to give a static interpretation to words used in a tariff schedule ignoring the rapid march of technology. Having regard to the technical opinion that reed switches would improve the performance of hearing aids, the High Court held that reed switches were covered by the tariff entry.** The High Court also noted that it was not the case of the Customs authorities that the respondent was trying to divert the imported reed switches from the manufacture of hearing aids to another purpose.

4. We do not think that we can put it better. Progress cannot be stifled by an over-rigid interpretation of Import Policy or Customs Tariff. Both must be read as they stand on the date of importation and whatever is reasonably covered thereby must be allowed to be imported regardless of the fact that it was not in existence or even contemplated when the policy or tariff was formulated."

(emphasis supplied)

37. In **Ethnor**, it was noticed that it had imported one consignment of pregnancy detection kits and declared them to be "Elisa diagnostic test" and claimed benefit of a Notification. The department, on a scrutiny of technical

literature, found that the goods were immunoassay kits based on menoclonal antibodies for qualitative detection of HCG. It is in this context, that the Tribunal observed that improvement in the testing methods have to be also granted the benefit. The observations of the Tribunal are as follows:

> "9. **The point which is required to be considered is as to whether any advancement made in scientific field to bring out a new innovation and same having been recognised both in medical field and by licencing controller, will these factors negative the conclusion that absence of enzyme in the item by replacing it by a colour conjugate system, will be itself take away the item from the ambit of the description in the notification namely,** "Elisa Diagnostic Tests". The answer has to be given clearly in the negative. The reason being that "Elisa Test" refers to pregnancy test carried out on the urine of a pregnant woman. **The improvement has been made to make the test more clear and to make the results more positive. The experts have clarified and amplified that the imported item is an advancement in technology of "Elisa Test". This factor has been recognised by the Drug Controller, as noted by us and the Drug Licence itself clearly states that the item is a "Elisa Test".** There has been a clarification also from Dr. S.K. Das, Asstt. Commissioner (BHS) Ministry of Health & Family Welfare to the effect that "Cards ± O.S.HVG - urine from Pacific Biotech INC" is an immunoassay and works on the principle of Elisa. Thus it is a Rapid Elisa Diagnostic Test for Pregnancy Test."
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> **(emphasis supplied)**

38. It is not in dispute that the test kits imported by the appellant also detect HIV and is based on an advanced technology. When the intention of the Exemption Notification was to grant exemption to diagnostic kits for HIV

antibodies, there is no good reason why the test kits imported by the appellant for detection of HIV should be denied exemption.

39. Learned authorized representative appearing for the department however, submitted that in view of the judgment of the Supreme Court in **Commissioner of Cus. (Import), Mumbai** vs. **Dilip Kumar & Company**[16], the Exemption Notification has to be strictly construed, and if a person claiming exemption does not fall strictly within the description indicated in the Notification, he cannot claim exemption. The Supreme Court, after considering number of decisions, ultimately held:

> "52. To sum up, we answer the reference holding as under-
>
> (1) Exemption notification should be interpreted strictly; the burden of proving applicability would be on the assessee to show that his case comes within the parameters of the exemption clause or exemption notification.
>
> (2) When there is ambiguity in exemption notification which is subject to strict interpretation, the benefit of such ambiguity cannot be claimed by the subject/assessee and it must be interpreted in favour of the revenue.
>
> (3) The ratio in Sun Export case (supra) is not correct and all the decisions which took similar view as in Sun Export case (supra) stands overruled."

40. Learned counsel for the appellant, however, relied upon a subsequent decision of the Supreme Court in **Government of Kerala** vs. **Mother Superior Adoration Convent**[17] to contend that the beneficial purpose of an Exemption Notification has to be given full effect.

41. In **Mother Superior**, the Supreme Court observed that there was a line of authority which stated that even in tax statues, an exemption

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16. 2018 (361) E.L.T. 577 (S.C.)
17. 2021 (376) E.L.T. 242 (S.C.)

provision should be liberally construed in terms of the object sought to be achieved and if such a provision grants incentive for promoting economic growth or otherwise has some beneficial reason behind it, then the legislative intent is not to burden the subject with tax. The Supreme Court also noticed that constitution bench judgment of the Supreme Court in **Dilip Kumar** did not refer to the line of authority which made a distinction between exemption provisions generally and exemption provisions which have a beneficial purpose. The relevant portions of the judgment of the Supreme Court in **Mother Superior** are reproduced below:

> "**23. It may be noticed that the 5-Judge Bench judgment did not refer to the line of authority which made a distinction between exemption provisions generally and exemption provisions which have a beneficial purpose.** We cannot agree with Shri Gupta's contention that sub-silentio the line of judgments qua beneficial exemptions has been done away with by this 5-Judge Bench. It is well settled that a decision is only an authority for what it decides and not what may logically follow from it [see Quinn v. Leathem - [1901] AC 495 as followed in State of Orissa v. Sudhansu Sekhar Misra - (1968) 2 SCR 154 at 162, 163].
>
> **24. This being the case, it is obvious that the beneficial purpose of the exemption contained in Section 3(1)(b) must be given full effect to, the line of authority being applicable to the facts of these cases being the line of authority which deals with beneficial exemptions as opposed to exemptions generally in tax statutes. This being the case, a literal formalistic interpretation of the statute at hand is to be eschewed. We must first ask ourselves what is the object sought to be achieved by the provision, and construe the statute in accord with such object. And on the assumption that any ambiguity arises in such construction, such ambiguity must be in favour of that which is exempted.** Consequently, for the reasons given by

> us, we agree with the conclusions reached by the impugned judgments of the Division Bench and the Full Bench."
>
> **(emphasis supplied)**

42. It is seen that in **Mother Superior** the Supreme Court held that the beneficial purpose of an exemption must be given full effect to and the question that is needed to be asked is what is the objective sought to be achieved by the provision and then the exemption has to be construed in terms of such an object.

43. In the present case, the test kits imported by the appellant are diagnostic kits used for detection and prognosis of HIV virus in human body. Thus, a purposive interpretation has to be extended to the entry in the Notification so as to give the benefit of duty not only diagnostic kits for detection of HIV antibodies but to also other technologically advanced diagnostic kits used for detection and prognosis of HIV, as they serve the same purpose. The object and purpose behind the introduction of exemption to HIV kits was in public interest to support the high demand of healthcare at affordable prices and to curb the spread of HIV virus in India. The test kits are used for detection and prognosis of HIV-virus in a human body. These kits not only detect the presence of HIV infection, but being more sensitive and accurate are used for regular monitoring of the spread of HIV infection in the body and for identifying the failure of the first course of treatment. They also serve the same purpose. In fact, the test kits imported by the appellant support the larger public interest objective of the National Aids Control Programme aimed at halting and reversing the HIV epidemic in India.

44. What follows from the aforesaid discussion is that the test kits imported by the appellant would be entitled for exemption from BCD and

only 5% integrated tax as provided for in List 1 of the IGST Rate Notification would be payable by the appellant.

45. It would, therefore, not be necessary to examine whether the test kits imported by the appellant are classifiable under CTI 3822 00 19 as claimed by the appellant or under CTI 3822 00 90 as claimed by the department for this would be relevant only if the appellant was not entitled for exemption from BCD under the Exemption Notification.

46. The inevitable conclusion that follows from the aforesaid discussion is that the impugned order dated 20.12.2022 passed by the Commissioner (Appeals) holding that the imported test kits are not eligible for the benefit of the Exemption Notification or the reduced rate of IGST under the IGST Rate Notification cannot be sustained and is set aside. The appeal is, accordingly, allowed.

(Order Pronounced on **06.08.2025**)

(JUSTICE DILIP GUPTA)
PRESIDENT

(HEMAMBIKA R. PRIYA)
MEMBER (TECHNICAL)

Shreya