

F.No. 524/18/2017-STO(TU)
 Government of India
 Ministry of Finance
 Department of Revenue
 (Central Board of Indirect Taxes & Customs)
 Tariff Unit

North Block, New Delhi

Dated: 25.07.2022

To,

All Principal Chief Commissioners/Chief Commissioners of Customs/Customs (Preventive),
 All Principal Chief Commissioners/Chief Commissioners of Customs and Central Tax
 All Principal Commissioners/ Commissioners of Customs/Customs (Preventive)
 All Principal Commissioners/Commissioners of Customs and Central Tax

Sir,

Subject: Clarification on Electro-Chemiluminescence Immunoassay kits-Reg.

In relation to the benefit of exemption of duties accorded to Chemiluminescence Immuno Assay (CLIA) kits, the Board is in receipt of representations seeking a clarification on whether Electro chemiluminescence Immuno Assay (ECLIA) kits are covered under the ambit of CLIA diagnostic kits.

2. The relevant entries and the notifications are as below:
- a) Serial no 167(A) of Notification 50/2017(Cus) read with Serial no 57 of List 4
 - b) Serial no. 180 to Schedule I of Notification 01/2017(Integrated Tax-Rate) , read with Serial no 178 to List 1

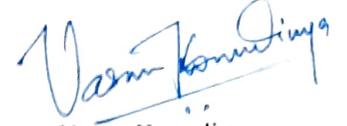
The notifications against the said serial numbers specify 'CLIA diagnostic kits'. However, there is no specific mention of ECLIA diagnostic kits.

3. The matter was examined in consultation with the Ministry of Health and Family Welfare(MoHFW). The significant points on which a clarification was sought from MoHFW and the response received are tabulated below:

S.No.	Clarification sought	Response from MOHFW
1.	How is a CLIA diagnostic kit defined? What are the different parameters that need to fulfilled to be considered as a CLIA diagnostic kit?	Chemiluminescence immunoassay (CLIA) is a widely used detection method which combines the highly-sensitive chemiluminescence assay with highly-specific Immune response and affinity of antibodies. In CLIA diagnostic kits, chemiluminescence technique is combined with immunochemical reactions. CLIA Kits are designed to detect the chemiluminescence reactions. In CLIA the label, i.e. the true "indicator" of the analytic reaction, is a luminescent molecule.

S.No.	Clarification sought	Response from MOHFW
2	Whether CLIA is a generic term that includes other technologies such as ECLIA etc.	CLIA have different label systems according to the difference of physical chemistry mechanism of the light emission which are mention below :-
3.	If yes, what are the other technologies that are considered to be included within CLIA	i. Label Chemical Directly Involved in the Light Emission Reaction ii. Enzyme Catalyzed Light Emission Reaction iii. Redox Reaction Mediated Light Emission Reaction (ECLIA).
4.	Whether an ECLIA diagnostic kit that is imported can also be used as a CLIA diagnostic kit.	CLIA and ECLIA (Electrochemiluminescence immunoassay) both, are advanced methods of Immuno diagnostics based on the concept of antibody- antigen binding. CLIA uses a chemical reaction to generate chemiluminescence following antibody-antigen binding while ECLIA uses an electrochemical reaction to generate chemiluminescence signals in the immunoassay technique. Both techniques are rapid, specific and similar in following points:-
5.	What are the parameters on the basis of which it is concluded that CLIA and ECLIA are one and the same.	<ul style="list-style-type: none"> • Both use the concept of chemiluminescence for detection. • Both techniques rely on the concept of antigen-antibody binding. • Both are mainly used for disease diagnostics based on analyte detection.
6	Whether CLIA and ECLIA kits can be considered the same and if the exemption granted to CLIA can be extended to ECLIA.	Chemiluminescence Immuno assay (CLIA) is a self sufficient kit which provides asensitive, high throughput alternative to conventional colorimetric methodologies. In Chemiluminescence Immuno assay (CLIA), the luminescence is produced as a result of chemical reaction where as in Electro ChemiluminescenceImmunoassay (ECLIA), theluminescence is produced as a result of electrochemical reaction. The CLIA and ECLIA canaccommodate many immunoassay principles while providing superior performance and theapplications, uses of both the techniques are same. Hence, both CLIA and ECLIA are one and the same.

4. The above clarifications from MoHFW clearly elaborate the various aspects of CLIA and ECLIA kits. It is advised that field formations take into account the above clarifications and make reasonable decisions on the assessment of the CLIA and ECLIA kits.
5. Hindi version follows.



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