29/Misc/03/2020-DC(288)
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated : 7 MAY 2021

To,
M/s. Cynosure Industries,
3 Mayfair Road Flat 1A
Kolkata West Bengal-700019.

Sub:- PMOPG/D/2020/0285320 of M/s. Cynosure Industries for introduction Air Ionization (CAIS) for the purpose of Decontamination and Sanitization on indoor environment –Regd.

Sir,

This is referring to PMO ID No. :PMOPG/D/2020/0285320 dated 03.12.2020 received by this office through Drugs Regulation Section, MoHFW vide P- 2023377/ 04/01/2021 regarding the above mentioned subject.

The case has been examined in the light of documents submitted by you. In this connection, it is stated that the product viz., **Cynosure Air Ionization System (CAIS)** used for decontamination and sanitization of pathogens including viruses at indoor environment is currently not under licensing as per Drugs and Cosmetics Act and Medical Devices, 2017 thereunder. However, as per the S.O. 648 (E) dated 11.02.2020 the proposed product falls under the definition of Medical Device.

In view of above, you may take action regarding voluntary registration for the product in portal established by CDSCO as per G.S.R. 102 (E) dated 11.02.2020.

Yours faithfully,

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to
Under Secretary (Drugs) w.r.t
PMO ID No. PMOPG/D/2020/0285320
representation from Shri Santosh Ghosh