

29/Misc/03/2021- DC (139)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation

To,

24 JUN 2021

Controlling & Licensing Authority,
Drugs Control Department,
Govt. of NCT of New Delhi.

Sub: Clarification regarding consideration of all medical devices as drugs-
Regarding.

Sir,

This is with reference to the email dated 29.05.2021 received from Drugs Control Department, Delhi in which it is requested to give clarification regarding the current status of medical devices which are to be covered under section 3(b)(iv) of the Drugs Act, 1940 with respect to W.P.(CrI) 975/2021 in the High court of Delhi.

In the said mail communication, you have mentioned that the interpretation of the Notification No.S.O.648 (E), dated 11.02.2020 is being considered in such a manner that all the medical devices including Oxygen Concentrators and Pulse Oximeters are being considered as drugs, and therefore under licensing regime, which is contrary to the spirit of notification no.GSR 102(E) dated 11.02.2020 which enlists only 37 medical devices and not all. Hence requested to provide suitable clarification regarding current status of medical devices which are to be covered under section 3(b)(iv) Drugs Act, 1940.

In this regard, it is stated that, as per S.O. 648(E) dated 11.02.2020 in pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, specifies the following devices intended for use in human beings or animals as drugs with effect from the 1st day of April, 2020, namely: — All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —

- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
- (iv) supporting or sustaining life;
- (v) disinfection of medical devices; and
- (vi) control of conception.

Oxygen Concentrators and Pulse Oximeters falls under the above said definition and will be regulated in phase wise manner as per GSR 102(E) dated 11.02.2020. Currently Oxygen Concentrators and Pulse Oximeters are not under licensing.

This is for your kind information.

Yours faithfully,



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