

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 2586
TO BE ANSWERED ON 06TH MARCH, 2020**

REGISTRATION OF VENTILATORS AND ANESTHESIA EQUIPMENT

2586. SHRI SUNIL KUMAR MONDAL:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the life saving equipment like ventilators and anesthesia work station are required to be registered under medical devices rules, 2017;
- (b) if so, the details thereof; and
- (c) if not, the reasons therefor?

**ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(DR. HARSH VARDHAN)**

(a) to (c): Central Drugs Standard Control Organisation (CDSCO) regulates the quality, safety and performance of notified medical devices under the provisions of Drugs and Cosmetics Act, 1940 and Medical Devices Rules, 2017 thereunder.

In order to bring all the non-notified Medical Devices under regulation, Government of India has, vide S.O. 648 (E) dated 11.02.2020, which will be effective from 01.04.2020, notified all medical devices intended to be used for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder, etc.,; as drugs under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

The Central Government has also amended Medical Devices Rules, 2017 vide G.S.R 102(E) dated 11.02.2020, effective from 01.04.2020, specifying that registration of all such medical devices will be in a phased manner.

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