

**GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA  
UNSTARRED QUESTION NO. 1603  
TO BE ANSWERED ON 10<sup>th</sup> February, 2023

**License for Software Medical Devices**

**1603. SHRIMATI KANIMOZHI KARUNANIDHI:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) the number of licences issued by the Central Drugs Standard Control Organisation (CDSCO) for software medical devices;
- (b) the data on the licences to import, sell, manufacture and clinically investigate, software medical devices, State-wise specially in Tamil Nadu;
- (c) the details on the types of software that have been granted medical devices' licences, based on speciality;
- (d) whether the use of software is regulated keeping in view the protection of digital medical data of the citizens; and
- (e) if so, the details thereof?

**ANSWER**

**MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS  
(SHRI BHAGWANTHKHUBA)**

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(a) to (b): Central Drugs Standard Control Organization (CDSCO) under the Department of Health and Family Welfare has granted import / manufacturing licences for Medical Devices and In Vitro Diagnostic medical devices that either incorporate electronic programmable systems, including software, or standalone software that are devices in themselves. Details may be seen at **Annexure**.

(c): The licenses granted for the medical devices either incorporate electronic programmable systems, including software, or standalone software that are devices in themselves such as.

- i. Blood Pressure Monitoring Devices,
- ii. Glucometer,
- iii. Digital Thermometer,
- iv. CT Scan Equipment,
- v. MRI Equipment,
- vi. PET Equipment,
- vii. X-ray Machine,
- viii. Dialysis Machine,
- ix. Defibrillators,
- x. Ultrasound Equipment,
- xi. Electrocardiograph,
- xii. Ablation devices,
- xiii. Bone Marrow Cell Separator, etc.

(d) to (e): Software Medical Devices, including In Vitro Diagnostic software, fall under the definition of a medical device as per S.O. 648(E) dated 11.02.2020, and are regulated under the provisions of Medical Devices Rules, 2017.

**Import/manufacturing licences granted as on 07.02.2023**

<b>Licence (Form Type)</b>	<b>No. of Approvals</b>	
	<b>India</b>	<b>Tamil Nadu</b>
Import licences (Form MD-15)	661	97
Manufacturing licences (Form MD-9 / MD-10)	34	03
Manufacturing licences granted by State Licensing Authority (Form MD-5 / MD-6)	118	04
For clinical investigation, the clinical investigation protocols are permitted rather than issuing the license. (Form MD-23)	03	00

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