

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

**LOK SABHA
UNSTARRED QUESTION NO.149
TO BE ANSWERED ON 21ST JUNE, 2019**

MEDICAL DEVICES

149. SHRIMATI RAKSHA NIKHIL KHADSE:

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

- (a) whether the Government proposes to cover the commonly used medical devices under the Drugs & Cosmetics Act to enable the Government to ensure their quality & performance and if so, the details thereof;
- (b) the list of the new medical devices added along with the devices notified earlier;
- (c) whether the Government also proposes to bring the high-end medical devices like MRI equipment, CT Scan equipment, X-ray machines etc. under the purview of drug law; and
- (d) if so, the details thereof?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (d): The Government has covered a number of medical devices under the Drugs & Cosmetics Act to ensure their quality and performance. The list of notified medical devices which are being regulated along with those which have been notified to be regulated from a specified date is annexed.

The list includes high end medical devices like MRI Equipment, CT scan Equipment, X-Ray Machines, etc.

ANNEXURE

S.No	List of notified medical devices which are regulated
1	Disposable Hypodermic Syringes
2	Disposable Hypodermic Needles
3	Disposable Perfusion Sets
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV
5	Cardiac Stents
6	Drug Eluting Stents
7	Catheters
8	Intra Ocular Lenses
9	I.V. Cannulae
10	Bone Cements
11	Heart Valves
12	Scalp Vein Set
13	Orthopedic Implants
14	Internal Prosthetic Replacements
15	Ablation Devices
16	Blood Grouping Sera
17	Ligatures, Sutures and Staplers
18	Intra Uterine Devices (Cu-T)
19	Condoms
20	Tubal Rings
21	Surgical Dressings
22	Umbilical tapes
23	Blood/Blood Component Bags
24	Organ Preservative Solution

S.No	List of medical devices notified and to be regulated from a specified date (as mentioned in the brackets)
1	Nebulizer (w.e.f 1 st January, 2020)
2	Blood Pressure Monitoring Device (w.e.f 1 st January 2020)
3	Glucometer (w.e.f 1 st January 2020)
4	Digital Thermometer (w.e.f 1 st January 2020)
5	All implantable medical devices Equipment (w.e.f 1 st April 2020)
6	CT Scan Equipment (w.e.f 1 st April, 2020)
7	MRI Equipment (w.e.f 1 st April 2020)
8	Defibrillators (w.e.f 1 st April 2020)
9	PET Equipment (w.e.f 1 st April 2020)
10	X-Ray Machine (w.e.f 1 st April 2020)
11	Dialysis Machine (w.e.f 1 st April 2020)
12	Bone marrow cell separator (w.e.f 1 st April 2020)