

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1931  
TO BE ANSWERED ON 29<sup>th</sup> DECEMBER, 2017**

**CLASSIFICATION OF MEDICAL DEVICES**

**1931. DR. BOORA NARSAIAH GOUD:**

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

- (a) whether the latest National Health Policy mandates to set up a regulatory body for medical devices;
- (b) if so, the reasons therefor;
- (c) the details of items classified as medical device;
- (d) the initiatives taken so far to set up one such body to oversee various aspects of medical devices in the country; and
- (e) whether all medical devices presently under Drug and Cosmetics Act would be brought under the new regulator and if so, the time by which it is likely to be materialized ?

**ANSWER**

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

(a) to (e): The National Health Policy, 2017 recommends strengthening regulation of medical devices and establishing a regulatory body for medical devices to unleash innovation and the entrepreneurial spirit for manufacture of medical device in India. The policy supports harmonization of domestic regulatory standards with international standards.

Presently 15 notified categories of medical devices are regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules 1945 thereunder, as per the details in the Annexure.

Ministry of Health & Family Welfare has notified Medical Devices Rules, 2017 for comprehensive regulation of Medical devices notified under the Drugs and Cosmetics Act, including their import, clinical investigation, manufacture, sale and distribution. The new rules are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices to foster India specific innovation and provide a fillip to Make in India.

<b>S.NO.</b>	<b>NAME OF DEVICE</b>
1.	Disposable Hypodermic Syringes
2.	Disposable Hypodermic Needles
3.	Disposable Perfusion Sets
4.	In vitro Diagnostic Devices for HIV, HbsAg and HCV
5.	Cardia Stents
6.	Drug Eluting Stents
7.	Catheters
8.	Intra Ocular Lenses
9.	I.V. Cannule
10.	Bone Cements
11.	Heart Valves
12.	Scalp Vein Set
13.	Orthopedic Implants
14.	Internal Prosthetic Replacements
15.	Ablation Devices