

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

**LOK SABHA  
UNSTARRED QUESTION NO. 1852  
TO BE ANSWERED ON 29<sup>TH</sup> NOVEMBER, 2019**

**REGULATORY FRAMEWORK FOR MEDICAL DEVICES**

**1852. SHRIMATI RAKSHA NIKHIL KHADSE:  
SHRI SUMEDHANAND SARASWATI:  
MS. PRATIMA BHOUMIK:  
SHRI BALAK NATH:  
DR. RAM SHANKAR KATHERIA:**

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

- (a) whether any commission or agency is operating at present to test the quality of medical devices like instruments, appliances, implants, pipes, thermometer etc. used during the treatment of humans and animals;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) whether the Government proposes to constitute a separate regulatory body for medical devices on the lines of medicines and if so, the details thereof;
- (d) the time by which the said regulatory body is likely to be constituted; and
- (e) whether the Government proposes to draft a bill to bring provisions of compensation for harm and injury and if so, the details thereof?

**ANSWER**

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

(a) & (b): 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. Ministry of Health and Family Welfare, Government of India designated five Central Medical Device Testing Laboratories for testing and evaluation of medical devices vide S.O. 2237(E), dated 01/06/2018. Further, CDSCO has registered four laboratories to carry out test and evaluation of medical devices on behalf of manufacturer.

Furthermore, Bureau of Indian Standards (BIS) also undertakes testing of such equipments as per their procedures.

(c) to (e): No such proposal has been approved by the Government.