

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:239
ANSWERED ON:26.07.2006
QUALITY CHECK OF MEDICAL DEVICES
Bishnoi Shri Kuldeep

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

- (a) whether there is any mechanism for quality check of medical devices being manufactured in the country;
- (b) if so, the details thereof;
- (c) if not, the reasons therefor; and
- (d) the steps taken by the Government to bring quality check on medical devices under the purview of Drug Controller of India?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (d): Yes Sir. In order to ensure quality check of medical devices manufactured in the country, a number of devices have been notified as 'drugs' under the Drugs and Cosmetics Act, 1940. The devices manufactured in the country are required to be manufactured in conformance to the standards prescribed under the Drugs and Cosmetics Rules, Bureau of Indian Standards or ISO. Ten more sterile medical devices have been recently declared as 'drugs' under the Drugs and Cosmetics Act, 1940. It has also been provided that these devices would be licensed for manufacture for sale or distribution by the Central Licensing Approving Authority appointed by the Central Government i.e. Drugs Controller General (India) .