

**GOVERNMENT OF INDIA
MINISTRY OF COMMERCE & INDUSTRY
DEPARTMENT FOR PROMOTION OF INDUSTRY AND INTERNAL TRADE**

LOK SABHA

**UNSTARRED QUESTION NO. 1417.
TO BE ANSWERED ON WEDNESDAY, THE 28TH JULY, 2021.**

ICMED PLUS SCHEME

**1417. SHRI JASWANT SINGH BHABHOR:
SHRI P.V. MIDHUN REDDY:
SHRI T.R.V.S. RAMESH:
SHRI M.V.V. SATYANARAYANA:
DR. SANJEEV KUMAR SINGARI:**

Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state:

वाणिज्य एवं उद्योग मंत्री

- (a) whether the Quality Council of India (QCI) has recently launched the Indian Certification of Medical Devices (ICMED) Plus Scheme;
- (b) if so, the details thereof;
- (c) whether the ICMED 13485 PLUS, will undertake verification of the quality, safety and efficacy of medical devices and if so, the additional features of this new scheme with respect to the previous scheme;
- (d) whether the new scheme would assist the procurement agencies to tackle challenges relating to the menace of counterfeit products and fake certification; and
- (e) if so, the details thereof?

ANSWER

वाणिज्य एवं उद्योग मंत्रालय में राज्य मंत्री (श्री सोम प्रकाश)

**THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE & INDUSTRY
(SHRI SOM PARKASH)**

- (a): Yes Sir.
- (b): Quality Council of India (QCI) jointly with Association of Indian Manufacturers of Medical Devices (AIMED) launched a voluntary certification scheme titled as 'Indian Certification of Medical Devices (ICMED) Plus' in June 2021. The scheme is meant to significantly eliminate trading of sub-standard products or devices. The criteria for certification under the scheme are in line with the internationally accepted mechanism of certification for Medical Devices.

- (c): The Scheme is aimed to help in verification of the quality and safety of the Medical Devices. The **ICMED Plus Scheme** is an upgraded version of ICMED Scheme. In addition to process certification, this scheme also takes care of product quality and product certification. It has a feature of performance verification of medical devices including biocompatibility, biological Safety, software verification and validation, animal studies, shelf life, etc. This initiative is aimed to equip the Indian manufacturers to upgrade themselves for meeting the international requirements of the importing countries.
- (d): This Scheme is aimed to assist the public procurement agencies with verified certification data.
- (e): The Scheme is aimed to be operated through accredited certification bodies in India who have competence to check both the process and product (medical devices) before grant of certification. The scheme will be governed by QCI and its Boards. A national register of certified products will be available for the procurement agencies, which is aimed to help traceability of all certificates issued under this Scheme.
