



More recognition for quality in Medical Device Sector in India

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When it comes to healthcare, people want the best in Service and Quality. Recently, Indians have been more cautious about what they buy regarding this sector. Increased awareness for quality makes it also necessary for producers to adopt standards and provide effective healthcare, at the same time reminding not to make costs too high for end users.

Currently, the healthcare market is estimated to grow to **US\$280** billion by 2020. It is also estimated to contribute **US\$160** billion to India's GDP by 2017, which would be a 4% share of the GDP. The healthcare industry consists of various segments, like hospitals, telemedicine, medical tourism and medical devices. In this industry, the medical devices sector is one of the fastest growing in the

recent years. But still, regulations were very unclear and the quality of products wasn't estimated very high by foreigners. India also imports **75%** of its medical device products. But now, the Indian Government wants to change the situation on this market, with respective outlook to '**Make in India**'. How is the Government helping to improve the Medical Devices Industry?

In March this year, a Quality Assurance Scheme, called Indian Certification of Medical Devices Scheme (**ICMED**) was launched cooperatively by the Quality Council of India (QCI), the National Accreditation Board for Certification Bodies (NABCB) and the Association of Indian Medical Devices Industry (AIMED). It is India's first indigenous quality assurance certification Scheme of this kind. The **implementation** of the Scheme is set to be concluded by the end of this year.

It is aimed to enhance the safety and trustworthiness of the devices being manufactured and registered in India in the future. In addition, it should reduce the time and cost for a company to obtain internationally accepted quality certification for its products. It is a step taken by the government that is appreciated a lot as the industry has long been penetrated by **sub-standard products** and fraudulent certificates, and is very fragmented, which makes controlling very hard. But this Scheme aims to improve patient safety and **consumer protection** along with the needed product credentials for Indian manufacturers. There are currently two different options for certification, one for low-risk devices and one for medium- and high-risk devices. The certification would be undertaken by **certification bodies** that are over sight of the NACBC to assure conformity with the regulations.

The **Secretary of the Department of Pharmaceuticals**, Dr. V.K. Subburaj, mentioned at the inauguration of the Scheme that it "fills a big vacuum in quality certification space for medical devices in the country and will enhance the competitiveness and profitability of Indian Medical Device industry". As a certification would now easier be accepted globally, the Scheme enhances the competitiveness of Indian Medical Devices as well. This could also boost exports in this sector, which is, as mentioned, still very dependent on imports.

Anyhow, the Scheme is only voluntary. So companies won't have to comply with the rules. But consumers knowing that the Scheme exists now can confirm that a product is certified and only buy these products. This will make it harder for companies which don't certify their products under the Scheme to stay competitive.

All in all, the Medical Devices Industry in India is expected to grow to **\$8.6 billion** by 2020. This Scheme supports the industry to become an internationally acknowledged sector with large growth potential.

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