

# MedtechUpdate India

December 2020

Market researchers are forecasting increased demand for medical technology in India. Economic expansion, a growing middle class, and political reforms are forces contributing to this development. At the same time, the Indian medical technology market is subject to relatively frequent and short-term regulatory interventions and new business are evolving. The export initiative for the German healthcare industry, HEALTH MADE IN GERMANY, set up MedtechUpdate India to ensure German companies are able to respond rapidly to changes in import, licensing, and marketing regulations. The English-language newsletter will appear regularly and provide the latest information on the most important new regulations for the medical technology market in India.

MedtechUpdate India is a service provided by HEALTH MADE IN GERMANY, the export initiative for the German healthcare industry, set up by the German Federal Ministry for Economic Affairs and Energy (BMWi).

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### 1. Government mandates license for import, manufacturing of four more medical devices

The Central Drugs Standard Control Organisation (CDSCO) has mandated that importers and manufacturers obtain a licence from the Central Licensing Authority or State Licensing Authority to import and manufacture nebulizers, BP monitoring devices, digital thermometers, and glucometers with effect from January 1. Last year, the Government had brought medical devices such as digital thermometers and blood pressure monitoring devices under Medical Device Rules (MDR) 2017, to address misdiagnosis. Post this notification, the industry made a representation to the CDSCO requesting it to extend the implementation for another three to six months because of the impending procedural requirements. The Government has given an extension to importers to obtain licenses for the notified medical devices. The CDSCO underlined that if an existing importer or manufacturer has applied for import/manufacturing license grant, they can continue to import or manufacture up to 6 months from the issue of this order.

**Relevance for German exporters and manufacturers:** *The decision came in view of a recent report highlighting that about 70% of digital blood pressure monitors used at homes are inaccurate. Another report released by The India Heart Study (IHS) revealed that 42% of Indians are at risk due to misdiagnosis of hypertension. Last year, the Government mandated that all medical devices be registered as ‘drugs’. The recent notification to extend the implementation*

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will allow Indian importers or distributors of foreign medical devices to seek the license in the next six months and to maintain seamlessness in their current operations.

**Link:**

[www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=Njc5Mg==](http://www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc5Mg==)

### 2. Government amends list of kits approved for COVID testing kits

The Central Drugs Standard Control Organisation (CDSCO) has updated and announced the new list of approved COVID-19 testing kits manufacturers, including foreign companies. Last month, the regulatory body published two separate notifications, enlisting approved testing kits manufacturers based on the category of kits with Rapid/CLIA/ELISA combined into one, and PCR type clubbed in another category. So far, 125 foreign testing kits manufacturers of Rapid/CLIA/ELISA type, including six from Germany, have been approved. These kits approved have been further classified into CLIA, Fluorescent Rapid ANTIGEN Test, iChrome FIA (Fluorescence Immunoassay) Covid-19 Ab, Anti SAR- COV-2 ELISA IgG, FIA iChroma IgG/IgM CE, and Standard Q COVID-19 IgG/IgM Duo, Chemiluminescent Microparticle Immunoassay with Architect System, Rapid Double Antigen test for detection of IgG/IgM/IgA and Vitros Immunodiagnostic Total Reagent Pack techniques. Additionally, 172 foreign PCR testing kits manufacturers, including seven German companies, have been approved.

**Relevance for German exporters and manufacturers:** Foreign manufacturers supply almost 75% of the approved testing kits meeting the quality and high demand for foreign testing kits for COVID-19 testing in India. The Indian regulator has highlighted CE-approved testing kit manufacturers; a decision that underscores the priority on the quality of testing kits. German exporters will benefit from the Indian Government's consistent focus and acceptance of CE approved kits.

**Link:**

[www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=Njc4NQ==](http://www.cdsc.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc4NQ==)

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### 3. CDSCO grants medical device registration to three GOQii wearables

The Central Drugs Standard Control Organization (CDSCO) has given approvals to GOQii's medical device registration of three wearables in Vital range, including Smart Vital, Vital 3.0, and Vital ECG. The California-based fitness technology firm's Smart Vital is a smartwatch that measures blood oxygen level and body temperature. The Vital 3.0 is a smart band that comes with the coloured display and measures blood pressure and body temperature. The Vital ECG provides ECG screening via tracker that can sync with the GOQii app to provide descriptive ECG reports to its users. The Government's recent decision aims to bolster the preventive approach to healthcare by encouraging foreign manufacturers to introduce new technology with an integrated assessment tool. GOQii seems to take advantage of India's smart medical device and wearable technology demand as it plans to move its manufacturing base to India. The firm has already shifted some assembly activities to India.

**Relevance for German exporters and manufacturers:** *Several domestic and global firms have entered into India's smart medical device and wearable industry through domestic manufacturing and exports, to capitalise on the emerging opportunities in the market. The CDSCO has taken protective measures to regulate the Indian medical devices industry by registering all medical devices. German manufacturers and exporters of smart wearable devices can explore the prevalent opportunity in this segment and subsequently register their devices with the CDSCO.*

**Link:** [www.businesstoday.in/technology/news/goqii-vital-device-range-gets-medical-device-registration-by-cdsco/story/423715.html](http://www.businesstoday.in/technology/news/goqii-vital-device-range-gets-medical-device-registration-by-cdsco/story/423715.html)

### 4. AIMED announces Medical Fair India, 2021: August 19 to 21, New Delhi

The Indian Association of Indian Medical Device Industry (AIMED) has announced the dates for the 27th edition of 'Medical Fair' to be held between August 19 and 21 at Pragati Maidan International Exhibition and Conference Centre, New Delhi. The 26th edition of the exhibition was cancelled because of COVID-19. Medical Fair India is an exhibition and conference for healthcare, attracting medical equipment manufacturers, exporters and other industry stakeholders from over 20 countries. The 2019 edition attracted 516 exhibitors (260 domestic and 256 foreign) from 17 countries and 14,875 visitors. The exhibition offers the latest range of products and solutions for medical, hospital and laboratory technology, diagnostic equipment, orthopaedic products and surgical instruments, as well as many other medical

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devices and solutions for pharmacies, hospitals, diagnostics, medicine, and rehabilitation. The event is organised by Messe Dusseldorf India, collaborating with the team of the world's largest medical fair Medica.

**Relevance for German exporters and manufacturers:** *The three days fair attracts participants from the medical technology and equipment industries of over 17 countries. The latest edition of the exhibition comes after a year gap and amidst the global pandemic, which has created an unprecedented need for closer cooperation of the industry stakeholders. German exporters and manufacturers of medical devices have an opportunity to participate in the exhibition and meet Indian importers and distributors of medical equipment and other industry stakeholders.*

**Link:** [www.aimedindia.com/events-activities/details?k=medical-fair-india-2021-25-to-27-february-2021-new-delhi-1301297820](http://www.aimedindia.com/events-activities/details?k=medical-fair-india-2021-25-to-27-february-2021-new-delhi-1301297820)

<https://www.medicalfair-india.com>

[https://www.auma.de/de/ausstellen/messen-finden/messedaten?tfd=new-delhi\\_medical-fair-india\\_203828](https://www.auma.de/de/ausstellen/messen-finden/messedaten?tfd=new-delhi_medical-fair-india_203828)

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