



Under MDR and IVDR

18 December 2020

## 100th TÜV SÜD certificate under the new medical device regulations

**Munich.** TÜV SÜD Product Service has now issued a total of 100 certificates under the new MDR and IVDR. After the first MDR certificates in September 2019 and the first IVDR certificates in October 2020, this marks a further milestone for TÜV SÜD. In addition, the first IVDR certificates in Asia overall have now been issued to Chinese manufacturers.

TÜV SÜD Product Service was designated for the MDR in May 2019 and the IVDR in June 2020. Since then, the international testing, inspection and certification (TIC) company has devoted every effort to supporting the smooth implementation of the two regulations.

Among the recipients of the 100 certificates issued under the regulations so far are manufacturers from four continents (Europe, North America, Asia, Australia) and a total of 14 countries – now including the first IVDR certificates in Asia and/or to Chinese manufacturers.

“The fact that we have now issued the 100th certificate under the new regulations perfectly demonstrates that TÜV SÜD is fulfilling its responsibility as a Notified Body to contribute to the ongoing supply of safe and effective medical devices for patients. With the resources we have built up, we are optimally prepared to master the challenges posed by high demand for MDR and IVDR services”, says Dr Jens Butenandt, Managing Director of TÜV SÜD Product Service GmbH.

### **TÜV SÜD – International expertise**

TÜV SÜD is one of the world's leading Notified Bodies, providing conformity assessment services related to medical devices. Its 900-plus medical device professionals can be found at more than 30 locations throughout the world. Manufacturers benefit from both TÜV SÜD's technical expertise and its extensive international accreditations and recognitions, including NRTL, INMETRO and the Medical Device Single Audit Program (MDSAP). These benefits considerably reduce the efforts involved in accessing international markets and time to market.

Further information about healthcare and medical devices at TÜV SÜD is available at :

<https://www.tuvsud.com/en/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification>

**Note for editorial staff:** This press release is available at: [www.tuvsud.com/pressreleases](http://www.tuvsud.com/pressreleases)

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Founded in 1866 as a steam boiler inspection association, the TÜV SÜD Group has evolved into a global enterprise. More than 24,000 employees work at over 1.000 locations in about 50 countries to continually improve technology, systems and expertise. They contribute significantly to making technical innovations such as Industry 4.0, autonomous driving and renewable energy safe and reliable. [www.tuv-sud.com](http://www.tuv-sud.com)