

Press Release

DEKRA Certification obtains official approval of European Commission

DEKRA Becomes First Notified Body in Europe for In-Vitro Diagnostics under New IVD Regulation

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DEKRA has become the first certification company to be recognized as a Notified Body by the European Commission under the new EU regulation on in-vitro diagnostics. Under this new regulation, considerably stricter requirements will apply to manufacturers of in-vitro diagnostics (IVDs) in the European Union starting from May 26, 2022. IVDs are medical products for laboratory testing of human samples.

DEKRA Certification GmbH, based in Stuttgart, is now the first company to be listed in the European Commission's NANDO database in accordance with EU Regulation (EU) 2017/746 on in-vitro diagnostics. The regulation was adopted in 2017 and will take effect on May 26, 2022. The procedure to be approved as a Notified Body is extremely complex and took around two years.

In the new version of Regulation (EU) 2017/746, the provisions on EU market access have been made considerably stricter. Several products for which a self-declaration was previously sufficient will require approval by a Notified Body from 2022 onward. There are also stricter rules on documentation, clinical evaluation and monitoring.

In August 2019, DEKRA Certification already became one of the first testing, inspection and certification companies to be appointed as a Notified Body under the new Medical Devices Regulation (EU) 2017/745. This regulation introducing stricter requirements for medical devices will already take effect on May 26, 2020.

About DEKRA

DEKRA has been active in the field of safety for more than 90 years. Founded in 1925 in Berlin as Deutscher Kraftfahrzeug-Überwachungs-Verein e.V., it is today one of the world's leading expert organizations. DEKRA SE is a subsidiary of DEKRA e.V. and manages the Group's operating business. In 2018, DEKRA generated sales totaling approximately 3.3 billion Euros. The company currently employs more than 45,000 people in more than 50 countries on all five continents. With qualified and independent expert services, they work for safety on the road, at work and at home. These services range from vehicle inspection and expert appraisals to claims services, industrial and building

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inspections, safety consultancy, testing and certification of products and systems, as well as training courses and temporary work. The vision for the company's 100th birthday in 2025 is that DEKRA will be the global partner for a safe world.