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FOR IMMEDIATE RELEASE January 5, 2022
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TÜV NORD Cert (CE 0044) ***is now designated for the Medical Device Regulation EU (MDR) 2017/745.***

Salem, New Hampshire January 4, 2022 -- TUV USA, Inc. is proud to announce TÜV NORD Cert's designation to EU (MDR) 2017/745.

TÜV NORD Cert has joined the list of notified bodies designated under the European Medical Device Regulation (MDR). We are now accepting applications and are ready to start the review of medical devices for the MDR under our German-based notified body (0044).

The MDR was published in the Official Journal of the European Union on May 5, 2017 with a three-year transition time. Due to the pandemic, the official date of implementation was delayed for one year to May 26, 2021. The MDR replaced directive 93/42/EEC Medical Device Directive (MDD) as well as 90/385/EEC Active Implantable Medical Device Directive (AIMD). Medical devices subject to the MDD and AIMD requirements are now subject to the new requirements under MDR.

The complexity of the transition from the MDD to the MDR, coupled with the delays caused by the pandemic, are proving to be a challenge for industry and for notified bodies. We at TUV USA, Inc. in conjuction with TÜV NORD Cert have been working hard behind the scenes to make the transition as seamless as possible while understanding the complicated nature of the process.

The first step is the application. Medical devices that require the involvement of a notified body will need to be evaluated and approved. Previously approved devices will need to be re-evaluated, re-approved, and in each case an application will be required. For your convenience, we have published the application **here.**

Our staff will review all applications and provide a non-binding quotation based on the size of the organization, the classification of the device(s), the product specifications, and other considerations. It is important to note that an assessment of the technical documentation must be performed prior and, in some cases, during routine audits.

Due to the time consuming nature of the MDR process, we urge manufacturers to plan ahead and submit your MDR application as soon as possible.

*Day rates may vary regionally.Contact your regional office for more information.

For general information regarding MDR, please visit:

Europa

TÜV NORD CERT's Europa MDR Page
EUROPA - European Commission - Growth - Regulatory policy – NANDO

For codes related to TNC (0044):
TNC Codes

MDCG (Medical Device Coordination Group) Guidance Documents:
Guidance - MDCG endorsed documents and other guidance | Public Health (europa.eu)

For questions regarding codes, products, etc. please contact:
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