

MDR Current State of Designation TÜV NORD CERT

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The designation process for the Notified Bodies under the MDR comprises numerous stages and iterative circles.

The process is initiated by a application prepared by the Conformity Assessment Body (CAB) in order to receive the designation as a Notified Body (NB) under the MDR.
The entire designation process is documented in the NBOG BPG-01 (see attachment 2).

The earliest date for application under the MDR was the 2017-11-26. Some of the previous Notified Bodies under the AIMDD/ MDD / IVDD sent their application to the EU Commission exactly that date, another greater group decided to launch the application later to benefit from the experience of the early applications.

TÜV NORD CERT has applied November 23rd 2018. After filing the application with the designating authority which is in Germany the “Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten” (ZLG), the application and supporting documents were assessed by ZLG and the preliminary assessment report submitted to the Joint Audit Team (JAT).
Based on the application assessment the JAT planned and performed the “on-site assessment that was performed” in October 2019 based on the assessment plan.

For the non-conformities identified during the audit of the JAT the CAB has to prepare a “corrective and preventive action plan” (CAPA plan) and submit this for further assessment to the JAT, who themselves start the iterative discussion on the proposed CAPA with the designating authorities.

TÜV NORD CERT submitted the CAPA plan 2019 and received several requests for further documentation by both parties EU JAT and ZLG. All of this additionally requested information was submitted for further assessment.

As there was no further request to submit additional documentation or evidence we assume that the current status of TÜV NORD CERT’s application is close to JAT final opinion.

The Commission is preparing regular publications with the “Overview of NBs at each stage of the process. This publications do not include any timelines when the next stage will be reached neither does it include any estimations concerning the expected date of designation for any individual applicant.

According to the stage plan provided by the NBOG BPG-01 TÜV NORD CERT’s application has to go through 3 further steps to go until the notification process ends.

The latest publication was made on 2020-12-07 (see attachment 1). The estimated current stage of TÜV NORD CERT’s application is indicated with an arrow.

All we can confirm at present about the status of TÜV NORD CERT designation is that CAPA plans are under final review and DA final report currently being complied. We trust that the final steps in the designation process will be initiated soon.

At this point in time we have no indication from the JAT or designation authority when we may expect the designation. We will update this status statement as soon as we receive further information.

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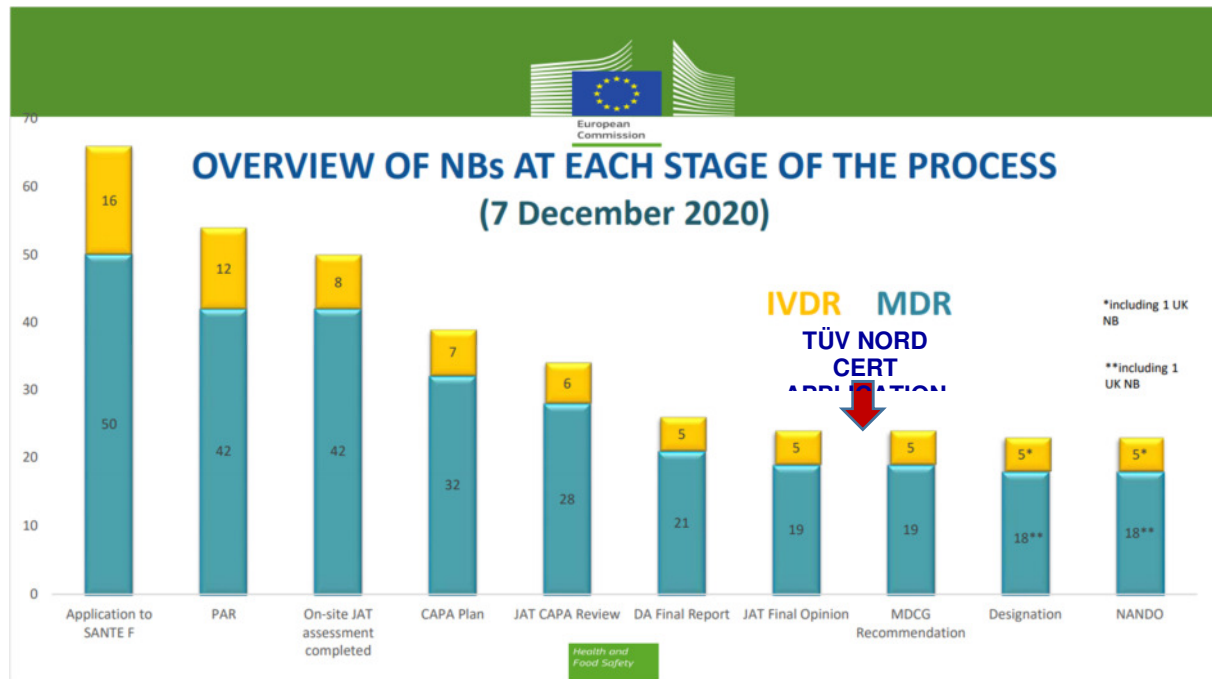
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Annex 1

Situation in December 2020:

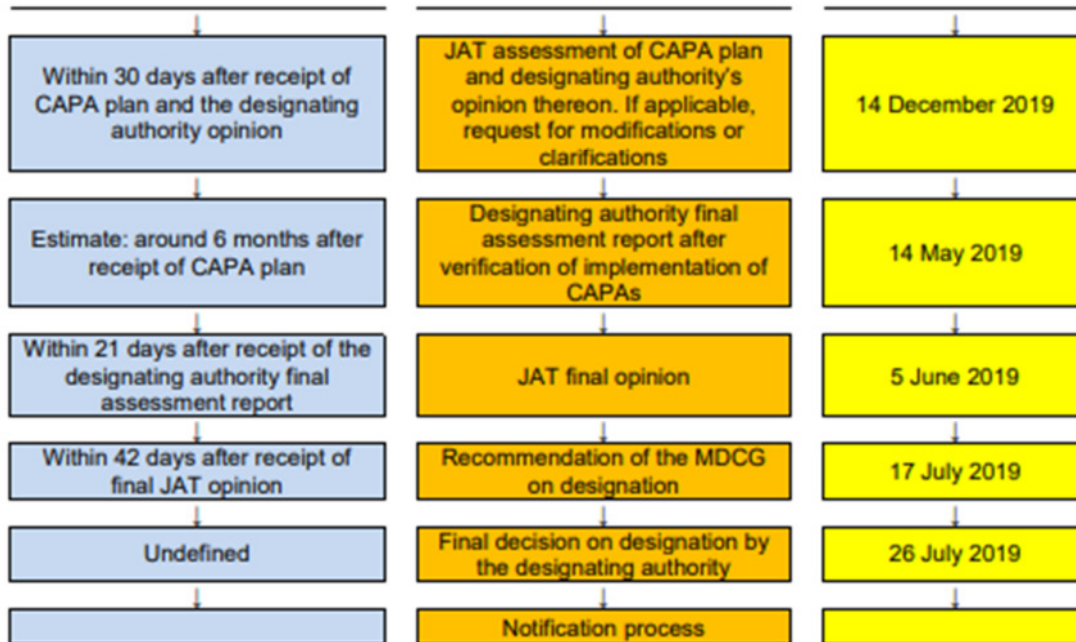
According to the publications by COM:



Annex 2:

Annex 1: Flowchart of activities and times





Remark:

The dates identified in this flowchart are based on the plans that were prepared prior to the first date of application and they are based on a scenario where the application by the CAB was submitted exactly on the first date of application.