

NB Designation under IVDR/MDR: State of Play*

Stages of the NB designation procedure	(1) Complete applications received by DG SANTE	(2) Pre-assessment/ Off-site activities <i>Designating Authority Preliminary Assessment Report</i>	(3) On-site assessments <i>Audits by Joint Assessment Team (JAT)</i>	(4) Post on-site assessments <i>JAT CAPA plan reviews issued</i>	(5) Final Designating Steps <i>MDCG Recommendations</i>	Notifications published in NANDO
Total	58 <i>~45 Notified Bodies in total</i>	49 <i>~85% of applications</i>	48 completed +1 pending <i>19 CAPA plans to be submitted</i>	25 <i>3 CAPA plans JAT rev. pending</i>	18	18
IVDR	14 <i>60% of IVDD designated NB</i>	8	8	5	4	4
MDR	44 <i>86% of MDD designated NB</i>	41	40 <i>+1 pending</i>	20	14 <i>+ 1 pending</i>	14

*Information based on [Team-NB](#) and [European Commission](#) information

Scope coverage ([NANDO](#)): overall, the entirety of MD and IVD codes