

# NB Designation under IVDR/MDR: Overview\* [Nov. '17- Oct. '19]

Stages of the NB designation procedure	(1) Complete applications received by DG SANTE	(2) Pre-assessment/ Off-site activities <i>e.g. Designating Authority Preliminary Assessment Report</i>	(3) On-site assessments  <i>Audits by Joint Assessment Team</i>	(4) Post on-site assessments <i>CAPA: Corrective &amp; Preventive Action</i>	(5) Final Designating Steps <i>e.g. MDCG Recommendations</i>	Notifications in NANDO
	From PAR to JAT final opinion 13 months				2 months	
<b>Total</b> <i>~ 40 Notified Bodies in total</i>	<b>51</b>	<b>46</b> <i>~90% applications</i>	<b>46</b> <i>37 completed +9 planned</i>	<b>23</b> <i>20 JAT reviews, 9 DA, 9 JAT final opinions</i>	<b>9</b>	<b>6</b> <i>Expecting 3 additional notifications by mid-Nov.</i>
<b>IVDR</b> <i>50% of IVDD designated NB</i>	<b>11</b>	<b>8</b>	<b>6</b> <i>(+2 pending)</i>	<b>5</b>	<b>2</b>	<b>1</b> DEKRA DE
<b>MDR</b> <i>85% of MDD designated NB</i>	<b>40</b>	<b>38</b>	<b>31</b> <i>(+7 scheduled)</i>	<b>18</b>	<b>7</b> <i>Positive MDCG recommendations</i>	<b>5**</b> BSI UK TÜV SÜD DEKRA DE IMQ TÜV Rheinland

\*Information based on Team-NB and European Commission information  
Scope coverage: overall, the entirety of MD and IVD codes

\*\* By end-2019: forecast ~20 NB designations (IVDR and MDR) expected by European Commission