



The European Association Medical
Devices - Notified Bodies

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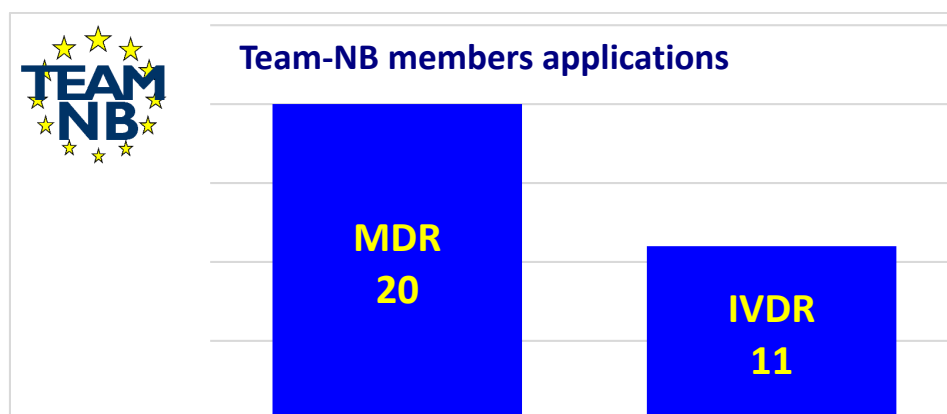
PRESS RELEASE

Survey on NBs applications against new regulations

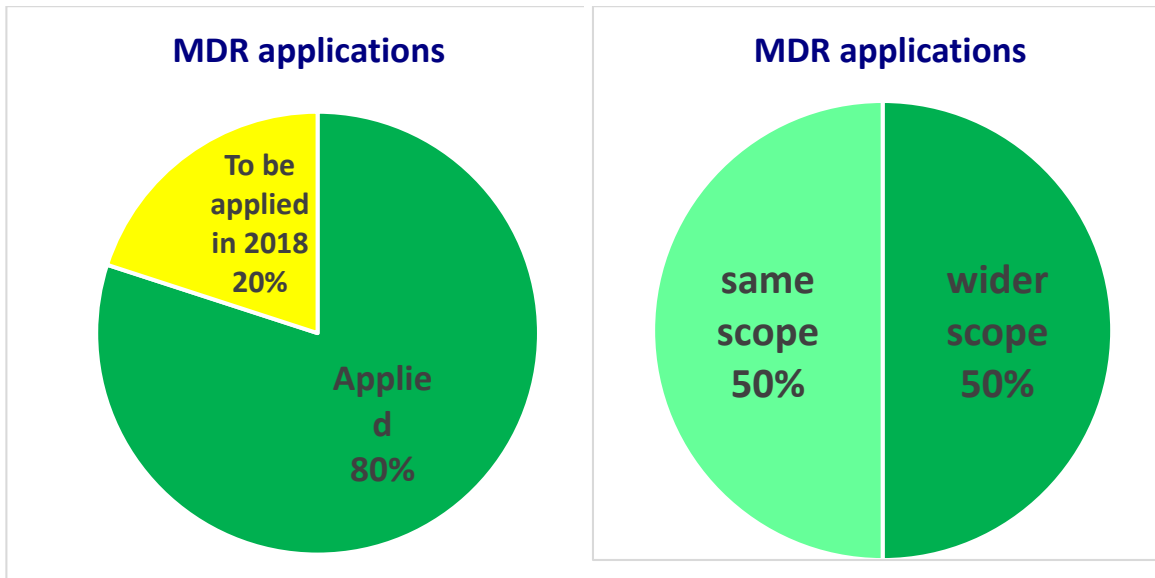
Following interest from the sector concerning the designation process in the framework of the MDR / IVDR regulations and as an act of transparency, you will find below data concerning the applications by the Team-NB member notified bodies under the MDR/IVDR and how this compares with their current scope under the three current directives AIMDD/MDD/IVDD.

For information-this data collection was completed on the 12th February. Twenty members were taken into consideration. It is to be noted that on one hand that our two Turkish members have not yet the possibility to apply as the regulations are not yet transposed into their national legislation and two of our current members will not apply as they will enter into a consolidated group with another notified body.

You will find below some commented graphs of this early 2018 survey.

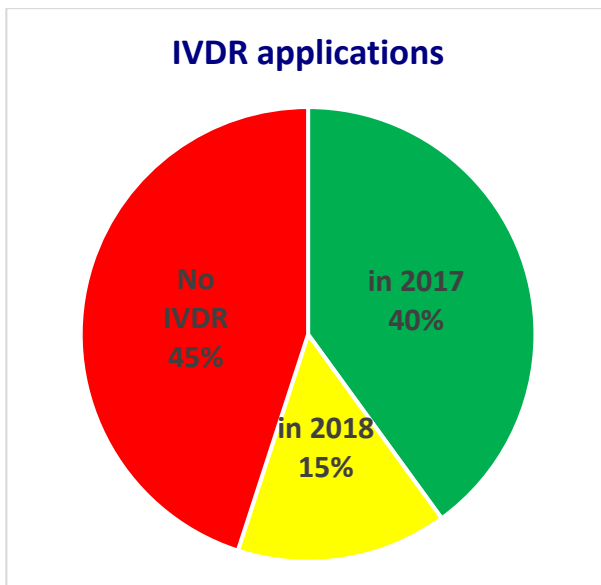


All the Team-NB members taken into consideration in this survey decided to submit an application to be designated against the MDR and 55% of them to be designated against the IVDR.



In the framework of the EU Medical Devices Regulation 2017/745

- ✓ 80% of the Team-NB members submitted their application to be designated against the MDR before February 12th, and
- ✓ Half of them applied for a wider scope, the other half for the same scope and none of them for a smaller scope.



In the framework of the In Vitro Diagnostic Regulation 2017/746

- ✓ 55% of the Team-NB members intend to submit their application to be designated against the IVDR, and among those
 - 73% submitted their application to be designated against the IVDR before February 12th, and
 - 27% will submit their application to be designated against the IVDR in 2018.
- ✓ and 45% do not intend to be designated against the IVDR.

As you can see, the results of this survey show the intent of the Team-NB members to do their best to allow the designation process to be as quick as possible.

In case of any further clarification needed, please contact secretary@team-nb.org.