

Editor : F. Schlemmer

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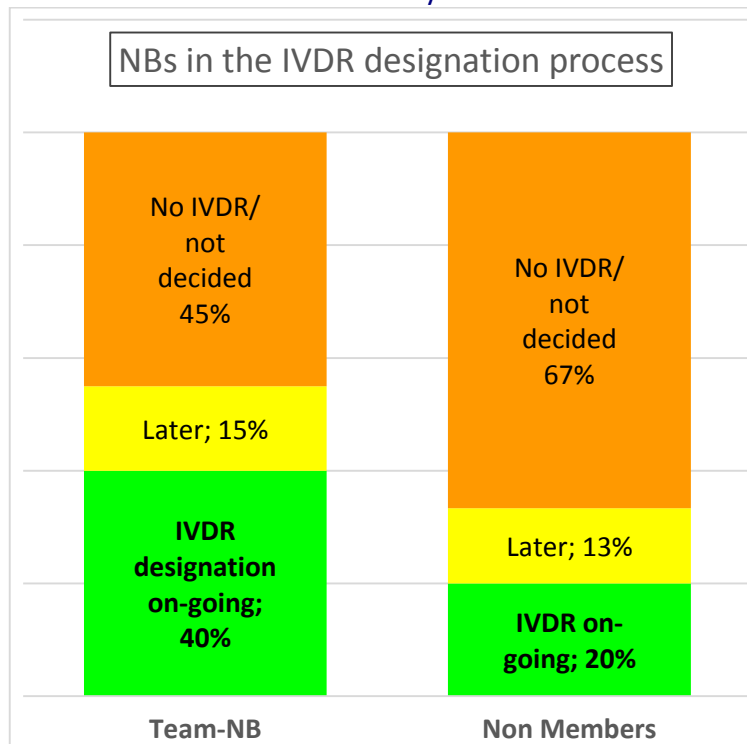
PRESS RELEASE
Survey on NBs applications against IVD new regulation

Following interest from the sector concerning the designation process in the framework of the IVDR regulation and as an act of transparency, you will find below data concerning the applications by 35 notified bodies both members and non-members of Team-NB.

This data collection was completed on the 11th January thanks to a survey tool in CIRCABC. The data relates to twenty members and fifteen non-members who responded to the survey. This has to be put in comparison with the today twenty-two notifies bodies designation against the IVDD.

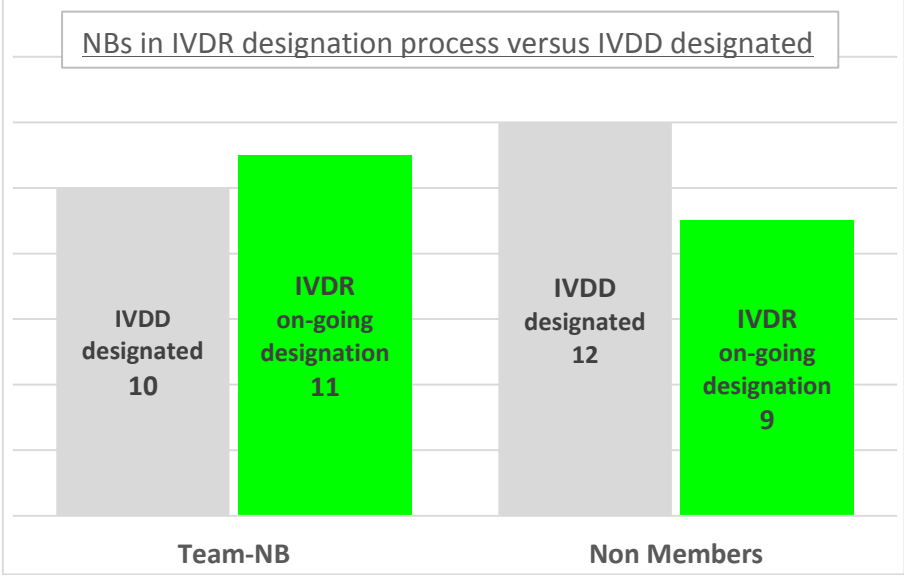
The below graph illustrate the **repartition** of notified bodies members and non-members **in or out the IVDR designation process**.

- Among the 20 Team-NB notified bodies members, 8 are in the designation process, 3 will apply later and 9 will not apply.
- And among the 15 non-members notified bodies, 4 are in the designation process, 6 will not apply and 2 have not made their decision yet.



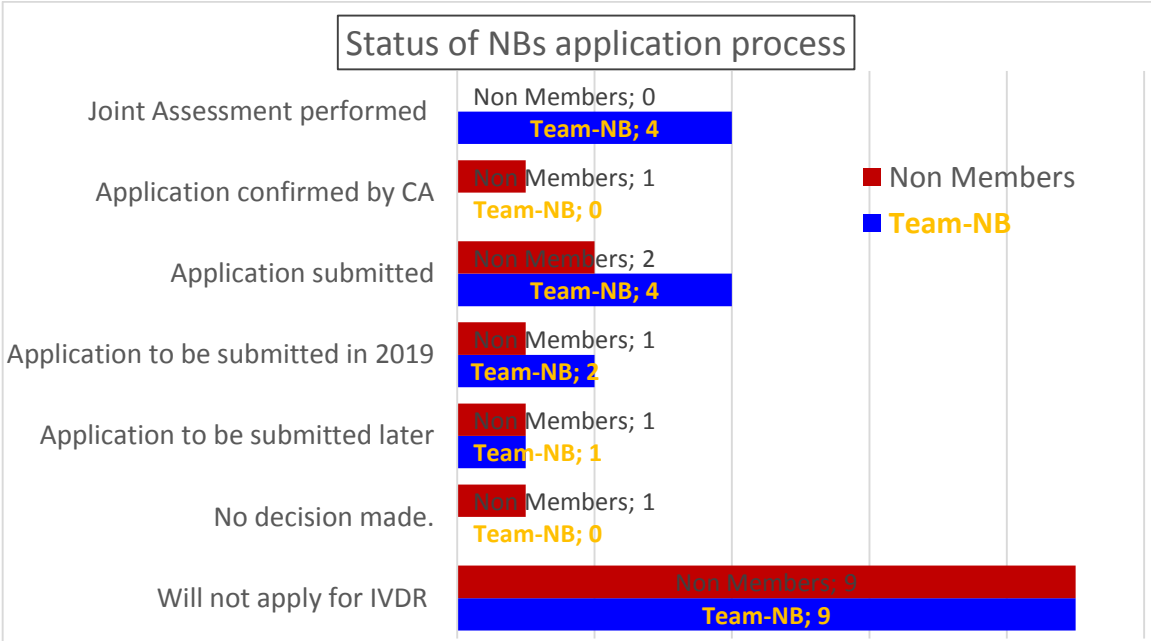
For reminder, in a former Team-NB survey, dated February 2018, where 22 members participated, 11 of them indicated that they intended to apply for designation against IVDR taking into consideration that 10 of them where already designated against IVDD.

In the below graph, the **intention** of the participants **to be designated against the IVDR** are compared to the today twenty-two notifies bodies designated against the IVDD.



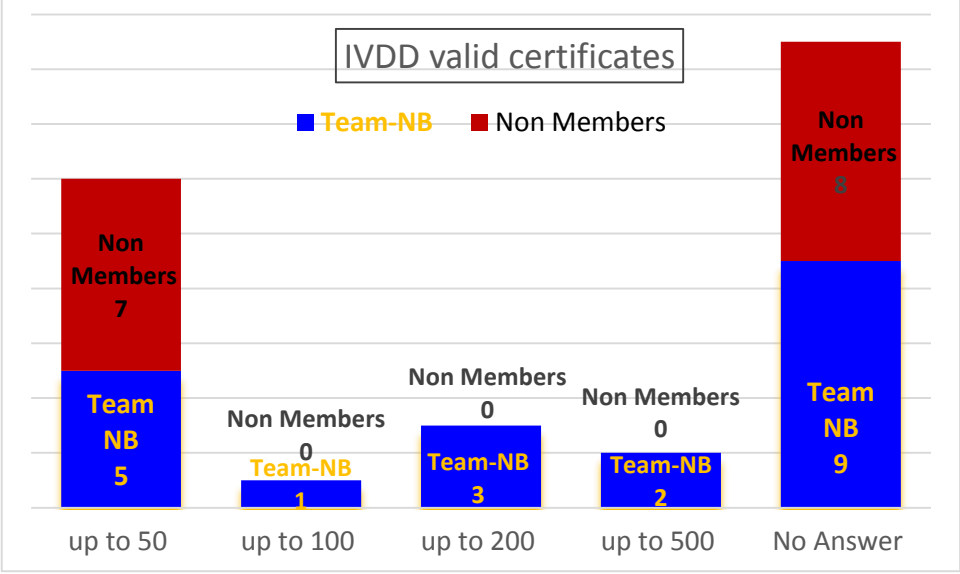
In order to precise the **steps in the designation process**, the survey asked the participants the status of their application. You will discover in the graph below the details.

In the graph, steps are listed in an ascending order with the one at the top closest to the designation, digits reflect the number of notified bodies in each step:



- The analyse shows that within the Team-NB ones which submitted their applications
- ✓ 4 of the members have already had the Joint audit, and are now in the process of addressing the observations,
 - ✓ 4 of the members have already submitted their application and
 - ✓ 1 will submit it later;
- And within the non-members which submitted their applications
- ✓ 1 has the completeness of his application checked by the Competent Authority (CA)
 - ✓ 2 have submitted their application and
 - ✓ 1 will submit it later.

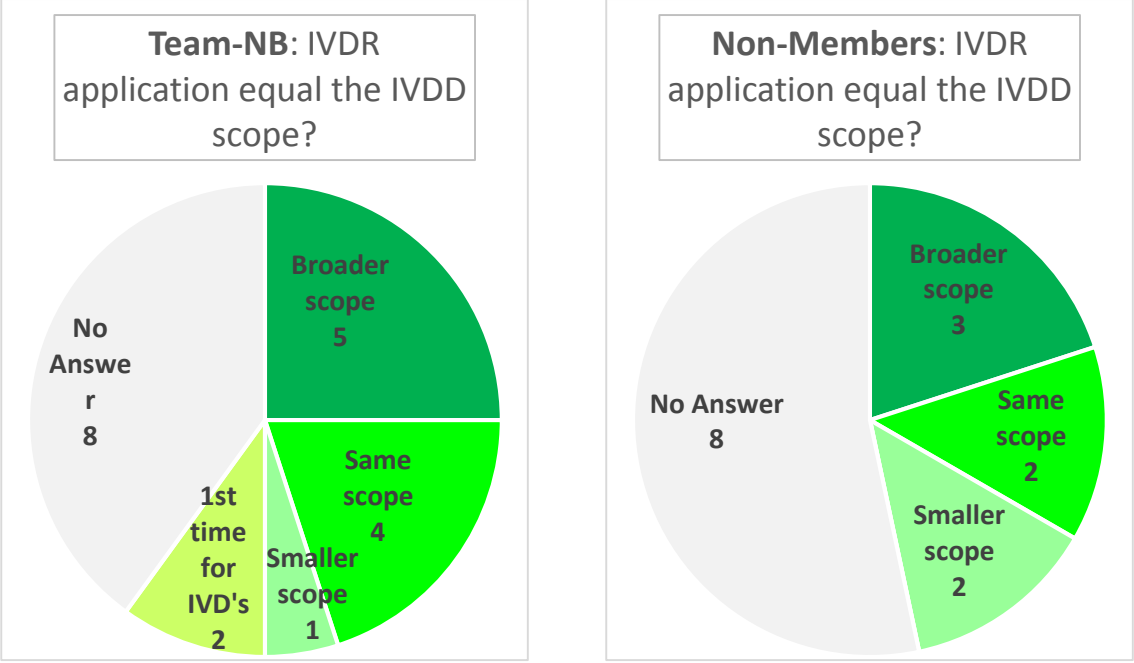
In answer to the question “How many certificates (IVDD) are currently valid?”, the below graph shows the result of the answers from the 2 groups of participants.



The answers show a larger number of certificates issued by the Team-NB members with among others

- 1 member which issued between 50 and 100 certificates,
- 3 members which issued between 100 and 200 certificates,
- 2 members which issued between 200 and 500 certificates.

As far as the scope applied area is concerned, in the answers to the question “Does the scope you applied for equals the existing scope mentioned in NANDO as of today?” we have noticed the following answers for both Team-NB members and non-members.



Moreover, in the answers to the question “What codes of products are covered by your application?”. We can see that **all the codes are covered** for both codes reflecting the design and intended purpose of the device and the horizontal codes.

In this framework, in more specific areas, we discover as far as the Team-NB members are concerned that

- ✓ 81% or more intended/intend to apply for all codes of devices intended to be used “which are controls without a quantitative or qualitative assigned value” and “in sterile condition”
- ✓ 69% or more intended/intend to apply for all codes of devices intended to be used “for markers of cancer and non-malignant tumours” and “for human genetic testing”
- ✓ 63% intended/intend to apply for all codes of devices intended to be used “to determine markers of infections / immune status” and “for non-infectious pathologies, physiological markers, disorders / impairments (except human genetic testing), and therapeutic measures”
- ✓ 56% intended/intend to apply for all codes of devices intended to be used “for blood grouping” and “for tissue typing”.

As you can see, the results of this survey confirm the intent of the Team-NB members to do their best to allow designation of notified bodies against the IVDR to be as quick as possible and covering all codes.

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