The European Association Medical Devices - Notified Bodies

TEAM-NB A.I.S.B.L.
Bd Frère Orban, 35A
4000 Liège - BELGIQUE
Tél.: + 32 (0)4 254 55 88

E-mail: secretary@team-nb.org
Web: http://www.team-nb.org
VAT : BE 0864.640.677
IBAN BE09 3401 5174 8757

Editor : F. Schlemmer Date : December 18th, 2018

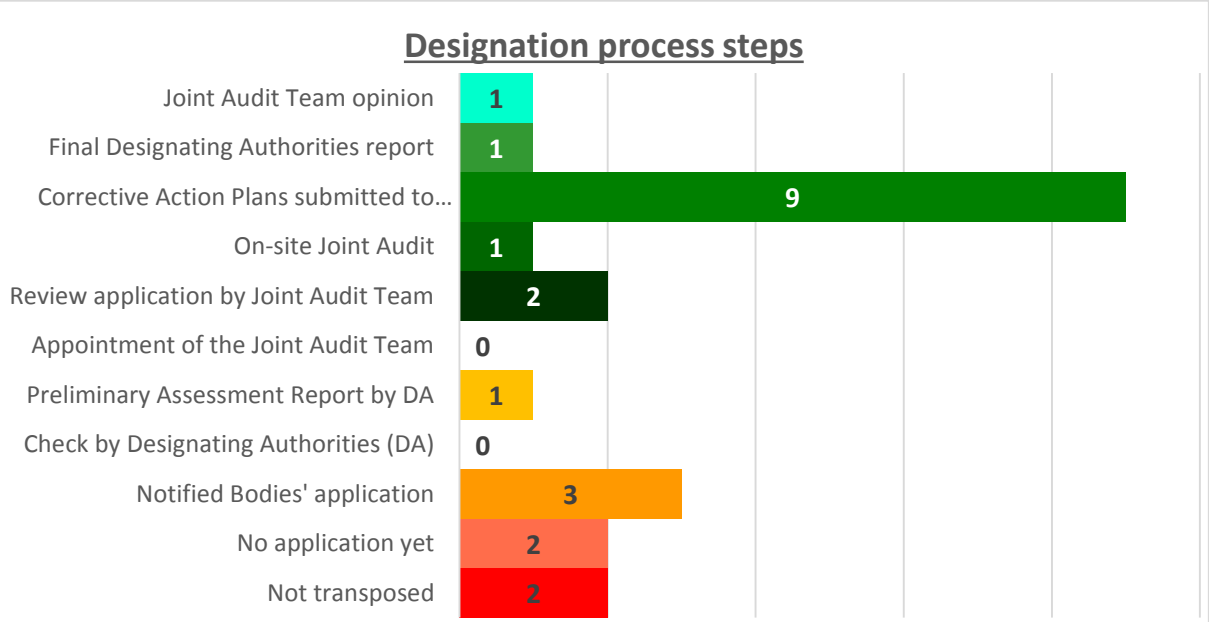
PRESS RELEASE

Surveys on MDR designation process steps
December 18th

Following interest from the sector concerning the designation process in the framework of the MDR regulations and as an act of transparency, you will find below data concerning the present stages in which Team-NB member notified bodies are, in the framework of the MDR.

This data collection took place between December 11th and December 17th.
The data relates to twenty-two members, who responded to the survey from a present membership of twenty-four members, out of 57 Notified Bodies currently designated for MDD and AIMD.

In the following graph, steps are listed in a descending order, digits reflect the number of notified bodies in each step :



In the framework of the EU Medical Devices Regulation 2017/745 on the basis of the 22 answers which are representing 92% of the members, we can extrapolate that

- ⇨ **82% of the Team-NB members submitted their application to be designated against the MDR.**

In the 22 answers of the Team-NB members

- 2 have not submitted their application yet to be designated against the MDR,
- 1 is going to merge with another notified body; and
- 2 are not in position to submit their application as the MDR has not been transposed in the Turkish law.

As you can see, the results of this survey confirm the work done by 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.