



How to find a Notified Body

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Status Notified Bodies (NB)

27 approved (2022-03-22)

- 2 in final stage
- 7 more with CAPAs (2022-12-14)

Based in the Nordic countries

- Finland, SGS Fimko, Eurofins
- Sweden, Intertek Medical Notified Body
- Norway, DNV Product Assurance



Other active Notified Bodies in Nordic countries

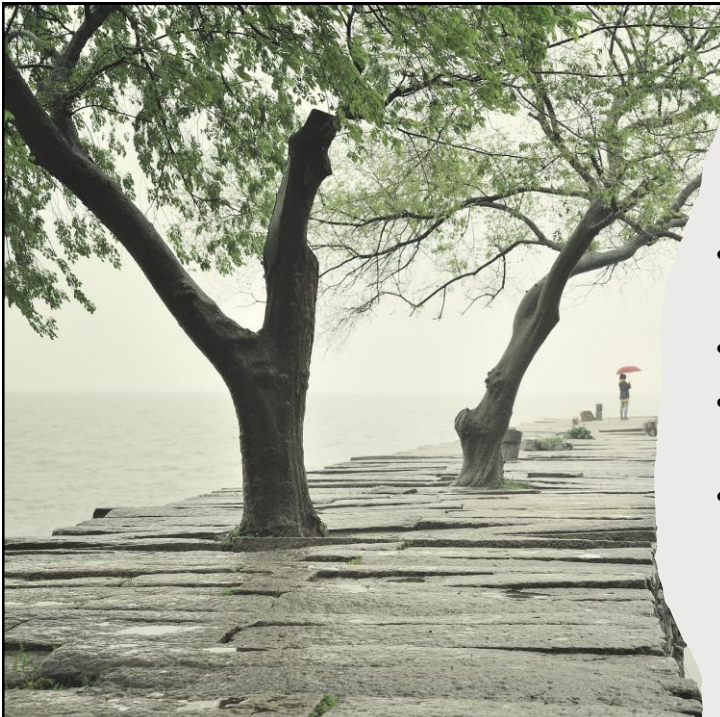
- A non complete list

- TUV Sud, Germany
- TUV Rheinland, Germany
- TUV Nord, Germany
- G- Med, France
- Bsi, Netherlands
- Dekra, Netherlands
- Dekra, Germany
- NSAI, Ireland



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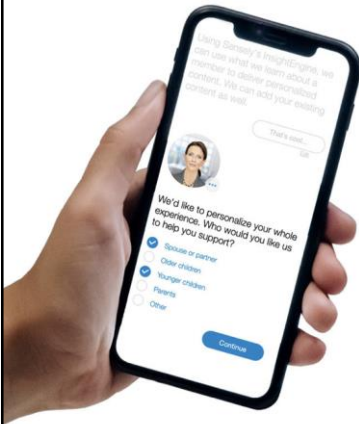
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Be aware of:

- NB`s are mostly "profit" companies.
- They have stretched resources
- They are not obligated to take you on!
- Not all NBs want to operate across EU

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Some products have more difficulties...

- Not a "main stream" product
 - often NB reviewer issue
- Software - reclassified products
 - classification, competence
- Switching Notified Body
 - Smoke rings... why you want to change

NBs must navigate many different aspects.
Currently they need to follow 19 MDCG and 6 NBOG guidance documents.

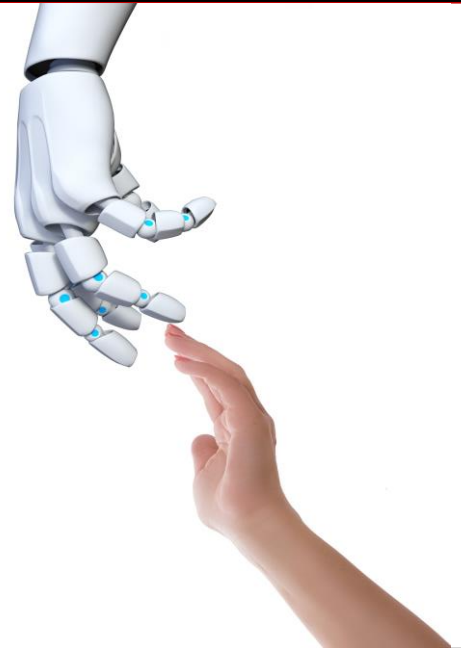
Think about the following

- NB culture - probably same as before
- Change to a new one can be burdensome
- Time to first approval vs recurrent changes approval time
- Not satisfied with current MDD notified Body?
 - Soon Last call to change, be aware of the risks



How to proceed - Setup a projekt

- Involve management and other functions
 - Professional project leader
- Document all attempts
 - Important in case you need help from authorities
- Approach the ones not yet approved



What to do?



- Make your list of prospect
- Call, Call, Call
 - Some NB's seldom answer or call back
- E-mails
- Try different routes to get inside!
- Visit tradeshow



Strategical considerations

Long Term vs Short term

- Service needs e.g. MDSAP
- Need for NB now?
- Future product portfolio

Customer service

- Fees
- Delivery time initial vs changes
- "Cooperation climate"

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Key take aways:

- This is a business project
- Most Notified Bodies answer you
avoid the ones not getting back in timely matter!

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