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# **Public Responsibilities of Notified Bodies**

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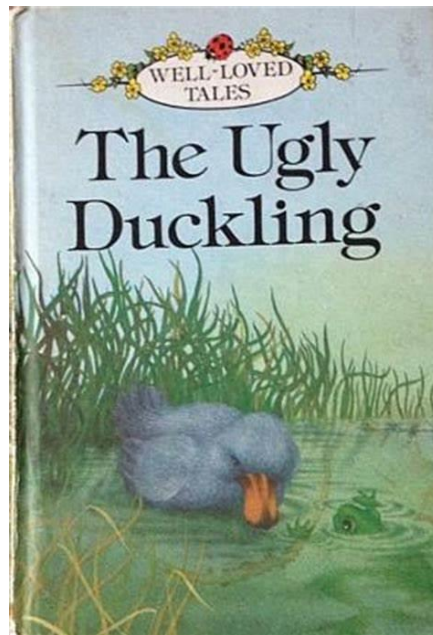
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# Introduction: fairy tale by H.C. Andersen

## “The Ugly Duckling”

- Different (from the other ducklings)
- Not well understood (by mother duck and by the other ducklings)

Are notified bodies “The Ugly Duckling” of the medical device regulatory system?



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# Agenda

- What are notified bodies?
- Performance of global regulatory systems
- MDR as gamechanger
- CORE-MD & Team-NB
- Conclusion



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# What are notified bodies?

- Semi-public or private organisations
- Executing legal tasks for medical devices in mid- and high-risk classes *on behalf of the authorities*
  - decisions on market access ('certification')
  - certain post-market monitoring tasks
- Mandated ('designated') by and under strict control of authorities
- Employing a vast array of experts in very diverse areas
- Fulfilling extensive legal requirements on
  - Training and authorization
  - Independence and impartiality



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# Vast amount of technical/scientific expertise

## MDR Annex VII 3.2.5

The personnel responsible for carrying out product-related reviews (product reviewers), such as technical documentation reviews or type examination, including aspects such as **clinical evaluation, biological safety, sterilisation and software validation**, shall have **all of the following proven qualifications**

- successful completion of a **university or a technical college degree** or equivalent qualification in relevant studies, e.g. **medicine, pharmacy, engineering or other relevant sciences**;
- **four years' professional experience** in the field of healthcare products or related activities, such as in **manufacturing, auditing or research**, of which **two years** shall be in the **design, manufacture, testing or use of the device or technology** to be assessed or **related to the scientific aspects** to be assessed;
- Notified body staff authorization procedures are based on a very granular medical device coding system
- Resulting in a work force with a big variety of very specific expertise



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# Performance regulatory systems

	EU	US#
Staff (FTE)	NBs: <b>5000</b> Authorities: ?	FDA-CHDR: <b>2300</b>
Devices 'cleared' for market access Oct 22-Oct 23	<b>2600</b> MDR certificates	PMA 2148
		HDE 82
		De novo 44
		<b>Total*</b> <b>2274</b>

# Data from FDA website  
\* Excluding 510k procedures



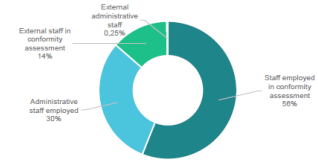
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## Staff: Number of people employed by NBs in the field of medical devices (MDR/AIMDD/MDD & IVDR/IVDD)

October 2023  
Total number of FTEs with conformity assessment activities and within administrative and supporting activities: 4,932.41



Notes:  
• Data status: 31/10/2023  
• By employee type  
• Counted in Full Time Equivalents (FTE)

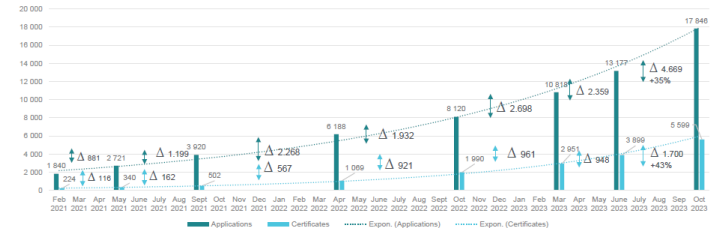
Employees within administrative and supporting activities  
(in relation to Regulations/Directives): 1,509.45 (FTE)  
• Internal: 1,496.95 FTEs (data of 39 NBs)  
• Externalised contractors: 12.5 FTEs (data of 38 NBs)

Employees within conformity assessment activities:  
3,422.96 (FTE)  
• Internal: 2,764.13 FTEs (data of 38 NBs)  
• Externalised contractors: 658.83 FTEs (data of 37 NBs)

Employees within the conformity assessment activities: is the personnel referred to in Sections from 3.2.3 to 3.2.7 of Annex VII MDR in addition to the personnel referred to in Section 4.4, second paragraph, of Annex VII MDR (individual responsible for ensuring that the assessment of that application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources including personnel are utilised for each of the tasks of the assessment.)  
Other roles would fit under employees within "administrative and supporting activities", including e.g. commercial operations team, marketing team, sales team, training team etc.

## MDR applications filed and certificates issued (sum of Annexes)

October 2023  
MDR Applications:  
Total number of applications filed by Annex M: 17,846\*  
MDR Certificates:  
Total number of certificates by Annex M: 5,599



Notes: October 2023: Designated NBs for MD: 39; NBs that included Annex XVI products in the numbers provided: 15  
\* The data shown comes from the medium data set (M) - except for 2 NBs where the total number of applications filed was derived from the small data set (S) since they could not provide the data per Annex.  
• a (Delta) = Difference in MDR Applications/MDR Certificates from one survey to the next one  
• Applications filed: This number includes all applications filed (syn. lodged) so far according to MDR Annex VII section 4.3 (from the day when the designation became valid, i.e. one day after publication in the Single Market Compliance Gazette to the date of the survey up to 31/10/2023), i.e.: applications with issued certificates, applications without decisions on the outcome of the conformity assessment activities, applications that were eventually refused or withdrawn by the manufacturer (including transferred applications), applications lodged for changes of existing MDR certificates. Pre-application activities are not included. One application can correspond to more than one certificate.  
• Certificates issued: This number includes certificates issued so far (from designation up to 31/10/2023) under the MDR.

Source: Notified bodies survey on certifications and applications - European Commission (europa.eu)



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# MDR/IVDR as gamechanger

## Whereas (4) MDR

Key elements of the existing regulatory approach, such as the **supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance** should be **significantly reinforced**, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, **to improve health and safety**.

### Resulting in significantly reinforced

- Notified body designation and monitoring
- Clinical data requirements pre- and post market
- Vigilance and other postmarket requirements
- Market surveillance by authorities
- Reporting and recording (many new documents and forms)

### And

- 'no grandfathering' for device market access and notified body designation
- complex, detailed regulation (legal text + > 80 guidance documents)



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# CORE-MD & Team-NB: mutual discovery journey

- At the start of Core-MD, Team-NB/notified bodies only involved in
  - **WP 4 Networking and community building: Engaging with stakeholders**
    - T4.3 Training, education, and capacity building /Educational objectives for stakeholders
- From there a ‘mutual discovery journey’ started
  - Notified bodies learnt that interaction with the medical/scientific community and clinical professional associations is a real asset
    - Example: Core-MD work on conditional certification
  - CORE-MD learnt that notified bodies staff is highly educated and trained rigorously and continuously according to legal requirements
- Resulting in productive cooperation
- “The future is bright”
  - Further exploration of potential for collaboration between the medical/scientific community and clinical professional associations and notified bodies
  - Mutual high expectations for continued cooperation in EU-funded projects



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## Conclusion:

Are notified bodies “The Ugly Duckling” of the medical device regulatory system?

- The other ducklings have discovered that notified bodies are not so different and better understand their role in the EU regulatory system
- Mother duck has discovered that the principles behind the EU regulatory system are really fostering health and safety and that notified bodies’ expertise is a key factor
- So the future is bright!

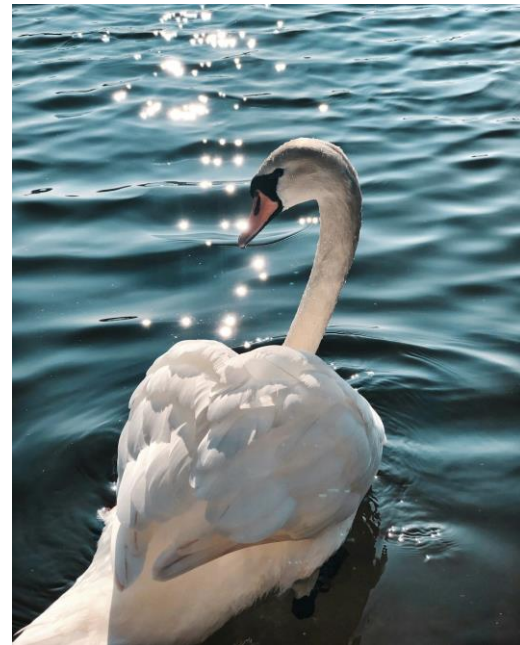


Photo by [Emily Sevenoaks](#) on [Unsplash](#)

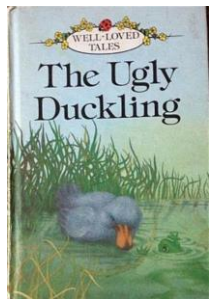


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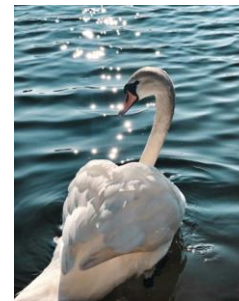
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Thanks for your attention!



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**CORE-MD**, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

 This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 945260

For more information, visit: [www.core-md.eu](http://www.core-md.eu)



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