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# UDI and Traceability EUDAMED

TÜV Süd Product Service  
Munich  
Hans-Heiner Junker  
International Affairs



Product registration will be required



UDI-DI & UDI-PI will be required in the future along with product registration



Attention: UDI and Basic-UDI – 2 different Codes



UDI: Traceability, on device



Basic-UDI: EUDAMED, regulatory purpose



- The timelines to implement UDI labelling are pending the realization of the EUDAMED Database, at the earliest:
  - Implants and class III in 2021
  - Class IIa / IIb in 2023
  - Class I in 2025
- Registration of devices with UDI codes and label product with UDI are 2 different requirements



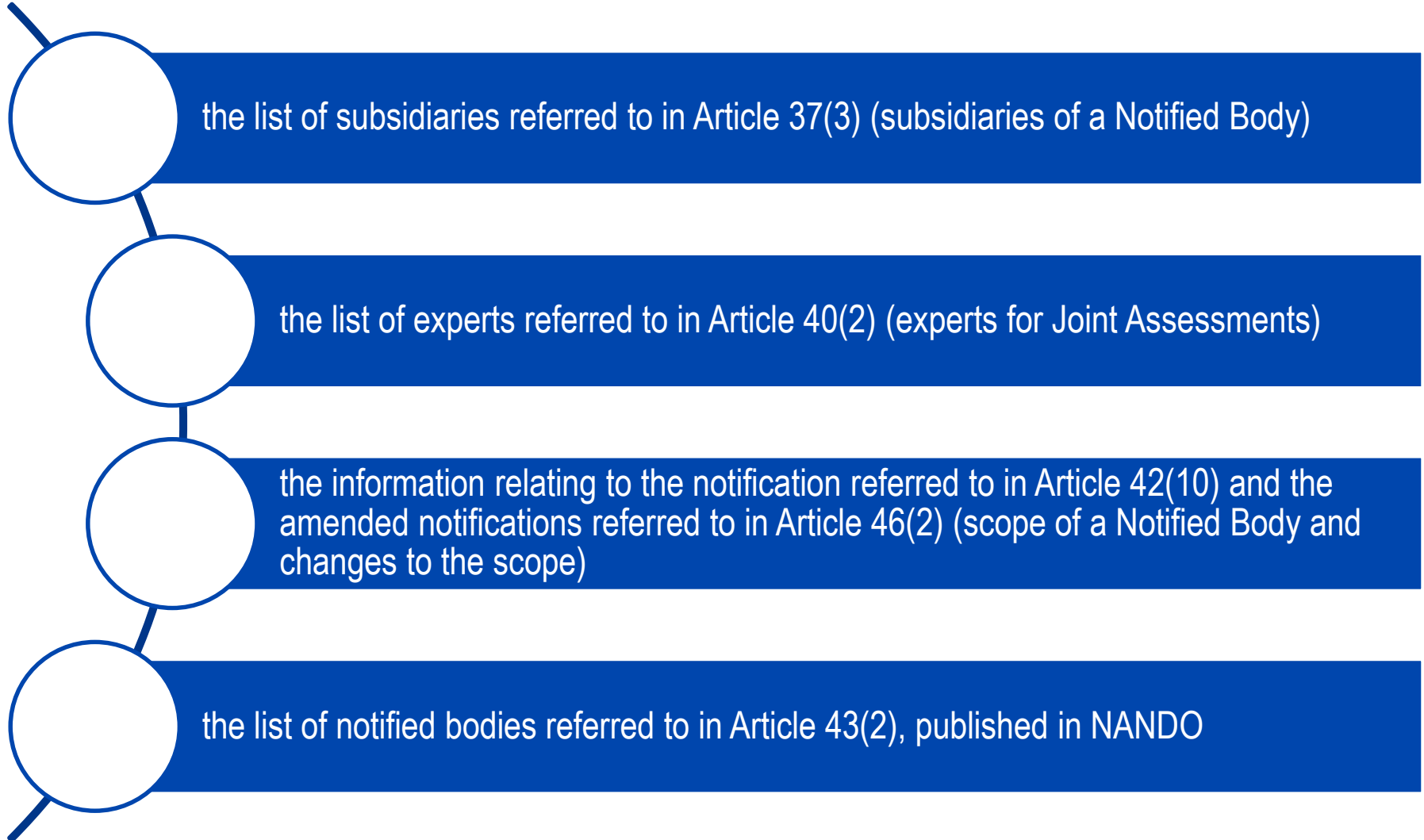
Enable the public to be adequately informed about **devices placed on the market**, corresponding certificates and the relevant economic operators.

The objectives of the database are to **enhance overall transparency**, including through better access to information for the public and healthcare professionals.

Enable unique **identification** and to facilitate **traceability** of devices within the internal market.

Enable public to be adequately informed about **clinical investigations** and to enable sponsors of clinical investigations to comply with obligations.

- Registration of economic operators (Article 31) [Manufacturers, Authorized Representatives, Importers]
- Registration of devices (Article 29) and UDI (Article 28)
- Notified bodies (Article 42) and on certificates referred to in Article 57
- Clinical investigations (Article 73)
- Vigilance and post market surveillance (Article 92 [PSUR, SSCP, FSCA...])
- Market surveillance (Article 100 [activities of authorities, e.g. inspections])
- Information on applications for conformity assessment and on certificates (Article 53 and 56) and on summaries of safety and clinical performance (article 32)



the summary of safety and clinical performance referred to in Article 32

the information regarding certificates referred to in Article 56(5);

withdrawal or refusals of applications for the certificates as referred to in Article 53(2) and Section 4.3 of Annex VII

the notifications for conformity assessments and certificates referred to in Articles 54(3) and 55(1)

the summary of the report referred to in Article 44(12)

## Article 123: **Entry into force and date of application**

- (d) without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could **not reasonably have been foreseen** when drafting the plan referred to in Article 34(1), **Eudamed is not fully functional** on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to **six months after the date of publication of the notice referred to in Article 34(3)**. The provisions referred to in the preceding sentence are:

-.....





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# Thank you

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