

IVDR: a new era for *In-Vitro* Diagnostic Medical Devices



Laura Nieto¹, Julie Vernier¹, Fabien JUSDADO¹, Alexia Marcone¹, Xavier Pineaux¹,
Sophie Salvat², Jeremy Rossin², Philippe Michel²

¹ Research and Development Life Sciences – Flow Cytometry, Beckman Coulter, Marseille France lnieto@beckman.com

² Quality and Regulatory Affairs Life Sciences – Flow Cytometry, Beckman Coulter, Marseille France ssalvat@beckman.com

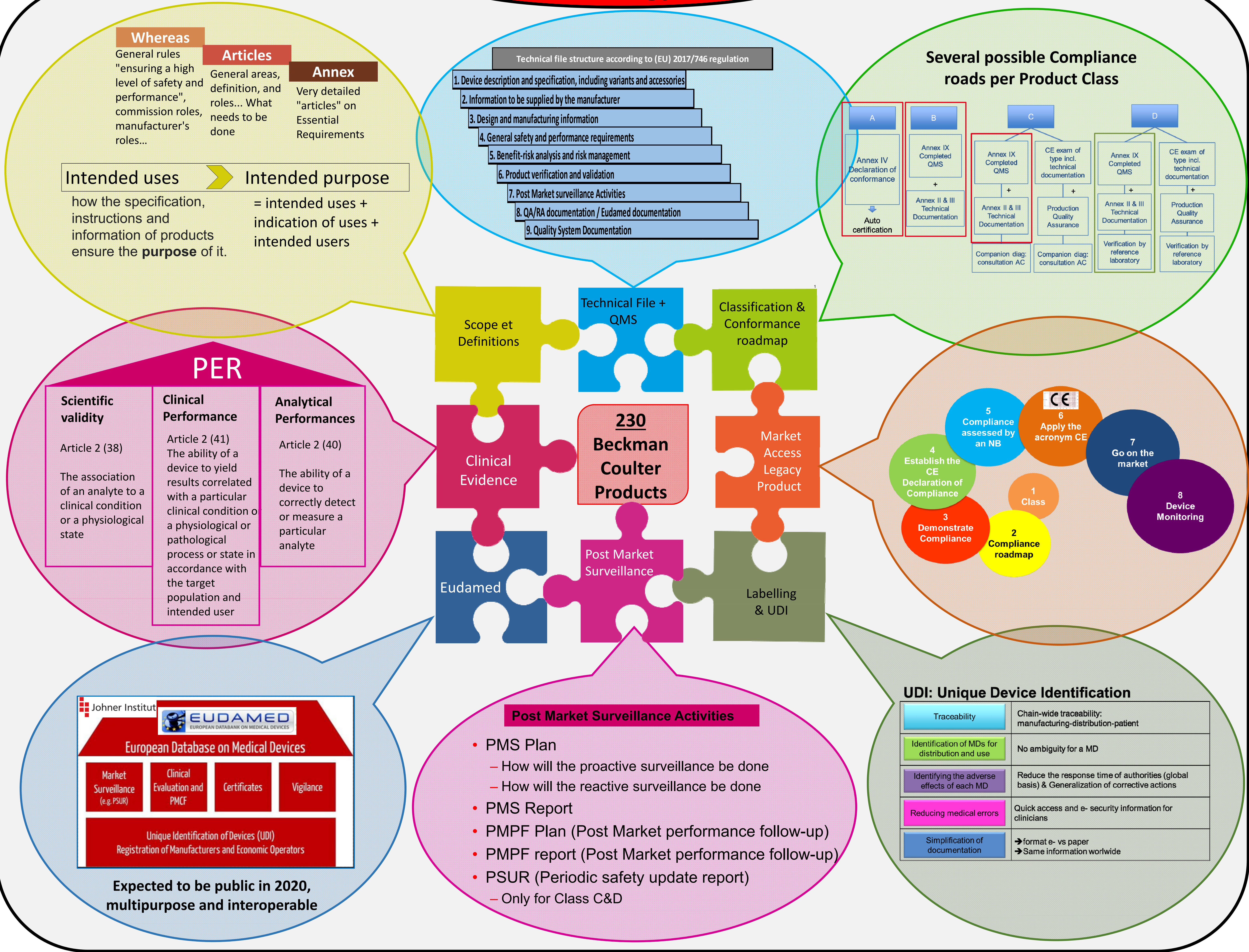
Introduction

- ✓ *In Vitro* Diagnostic Device Regulation (IVDR) is new European regulation for placing *in vitro* diagnostic medical devices (IVDMD) on the European market.
- ✓ Revision of the current Directive 98/79/EC was done to establish a **robust, transparent, predictable and sustainable** regulatory framework for IVDMD which ensures high level of safety and health whilst supporting innovation. This regulation sets high standards of quality and safety for IVDMD by ensuring, among other things, that data generated in performance studies is reliable and robust
 - Here we show a robust project plan to fulfill IVDR requirements of more than **230 IVD CE marked products for May 2022**

Aim

- Beckman Coulter (BEC) has put in place an intensive worldwide program across all Business Units (BU) in order to meet the quality and safety standards requirements in a timely manner. This Global IVDR program aims to identify and remediate impacts for all current BEC IVD products to comply with *In Vitro* Diagnostic Device Regulation.

Strategy



Conclusion

New IVDMD classification demands demonstration of strong clinical evidence, which resides in Analytical Performance, Scientific Validity and Clinical Performance. BEC Marseille IVDR team, in the framework of the IVDR Global program, has established and deployed a robust project plan to fulfill IVDR requirements of more than 230 IVD CE marked products for May 2022. One key of success is strong and open relationship between different stakeholders such as Quality/Regulatory Affairs, R&D, Manufacturing, Engineering and Marketing.