X.	**THE NEW EU IVD REGULATION (IVDR)**
	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical. **The In Vitro Diagnostic Regulation (IVDR) stipulates all requirements in vitro diagnostic medical device manufacturers will have to comply with. This regulation replaces the existing Directive 98/79/EC.** **Publication** **May 05, 2017: Publication in Official Journal of the European Union (EUOJ) - EU 2017/746 for IVDR** **Entry into force** **Publication of the new Regulation in EU Official Journal + 20 Days** **Texts take effect: 25 May 2017** **Date of application (DoA)** **'Transition period'** **5 years after entry into force for IVDR** **Full application for the IVD Regulation: 26 May 2022**
	The purpose of this training course is to enable you to understand the main points under the new IVDR: 1. **Key Changes** 2. **Extension of the concept of in vitro diagnostic devices** 3. **Classification structure** 4. **clinical evidence** 5. **Implementation of unique device identification UDI** 6. **Stricter requirements for Economic Operators** 7. **Common Specifications** 8. **Person responsible for regulatory compliance** 9. **Conformity Assessment** 10. **Greater scrutiny of Notified Bodies - Increased Notified Body involvement** 11. **Stricter Requirements Technical Documentation** 12. **Strict post-market surveillance**
	Our services include: **Upon completion of this course trainees will:** **I. be able to understand the basics points of the new IVDR;** **J. be able to understand the actual changes of the new IVDR;** **K. get familiar with the principles of new IVDR requirements.** **L. EU IVDR Implementation Consulting and maintenance** **Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up, support certification**
	References **Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical.**