EUROPEAN UNION: REGULATORY APPROVAL PROCESS FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

Determine the CLASSIFICATION of your IVD in accordance with the In Vitro Diagnostic Medical Devices Regulation (IVDR), Annex VIII **IVD**

Class A	Class B	Class C	Class D

Implement Quality Management System (QMS) in accordance with Annex IX of IVDR. Most companies apply the ISO 13485 standard to achieve QMS compliance.

Prepare a Technical File which provides detailed information demonstrating compliance with the In Vitro Diagnostic Devices Regulation (Annexes II and III)

Appoint an Authorized Representative (EC REP) located in Europe and qualified to handle regulatory issues. Place EC REP name and address on Instructions for Use and packaging wherever sold in Europe. **EC REP**

Register the manufacturer and the IVD in the EUDAMED database. As a result you will get the unique device identifier (UDI).

Your QMS and Technical File must be audited by a European Notified Body.* CE Marking certificate for your device will be issued upon successful completion of the Notified Body audit.**

Prepare a Declaration of Conformity, a legally binding document prepared by the manufacturer stating that your IVD is in compliance with IVDR. You may now affix CE Marking to your IVD. CE

CE certification does not expire as long as you remain in compliance with IVDR. Competent Authorities can inspect you at any time.

You will be audited by a Notified Body every 6-12 months to ensure ongoing compliance with the applicable Annex of 98/79/EC. Failure to pass the audit will invalidate your CE Marking certification.

Conduct ongoing batch testing and forward results to your Notified Body. **LOT**

*Notified Body - EU accredited third party authorized to control medical device companies and their devices.

**A CE Certificate (issued by a Notified Body) is not applicable to Class A devices since manufacturers will self-declare conformity with the Regulation EC 2017/745.