Regulation (EU) 2017/746 on in vitro diagnostic medical devices **(IVDR) Applicable conformity assessments per device class**

IVD: Device class & Certificate type		EU QMS Device or Group	EU TDA Device	EU TE Device	EU PQA Device or Group
Class D		✓ (NB)	✓(NB, SSP, scrutiny)		
				✓ (SSP, scrutiny)	✓
Class C	Self/near patient testing devices	✓(NB)	✓(NB, SSP)		
				✓ (SSP)	✓
	Companion diagnostics	✓(NB)	✓(NB, SSP)		
				✓ (SSP)	✓
	All other class C devices	✓ (SSP)			
				✓ (SSP)	✓
Class B	Self/near patient testing devices	✓(NB)	✓(NB)		
	All other class B devices	✓			
A sterile		✓			
					✓

29.3 par #1: MF assigns a Basic UDI-DI before it applies to a NB

29.3 par #2: NB confirms the concerned device data in registering the certificate in Eudamed.
As a pre-requisite the MF provides the NB identification and certificate type information with submission of Basic UDI-DI data in Eudamed.

(NB) = Same NB carries the conformity assessments.