SUMMARY OVERVIEW

SUMMARY TYPE	Summary of Safety and Clinical Performance (SSCP)		Summary of Safety and Performance (SSP)		
REGULATORY FRAMEWORK	MDR – Regulation (EU) 2017/745		IVDR - Regulation (EU) 2017/746		
MDCG REFERENCE	MDCG 2019-9 Guidance		MDCG 2022-9 Template		
PRODUCT TYPE	Medical Devices (MDs)		In Vitro Diagnostic Medical Devices (IVDs)		
INTENDED USE(R)S	Professionals	Patients/ Lay users	Professionals	Patients/ Lay users	Self-testing
REGULATORY RISK CLASS	Class III and implantable devices		Class C and Class D IVDs		
CONFORMITY ASSESSMENT	Pre-market validation required by Notified Body to confirm all required information is included in the summary and sourced from the most current version of the technical dossier.				
PUBLIC DISCLOSURE	• Validated master version uploaded to EUDAMED by the NB along with the certificate • Translated versions uploaded to EUDAMED by the NB within 15 days of receiving them from the manufacturer				
LANGUAGE TRANSLATIONS	• Single language required at NB validation, unless manufacturer's language is non-English in which case an English version is also required • All languages in scope of the medical device target markets for EUDAMED publication				