How Almac Diagnostic Services Meets Article 5 (5) of IVDR

Article 5(5)	**Almac Diagnostic Services**
With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:	
(a) the devices are not transferred to another legal entity;	ADS does not transfer in-house IVDs to another legal entity
(b) manufacture and use of the devices occur under appropriate quality management systems;	ADS manufacture and use the device under a QMS that is inclusive of ISO 13485, ISO 14971 and ISO 15189
(c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;	ADS is ISO 15189 accredited
(d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;	ADS have device and literature review procedures in place to ensure that there are no other equivalent devices available on the market
(e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;	ADS is ISO 13485 accredited (manufacturing under Design Control) and have the appropriate procedures in place, inclusive of change management. ADS will provide all information upon request to the MHRA
(f) the health institution draws up a declaration which it shall make publicly available, including: i. the name and address of the manufacturing health institution; ii. the details necessary to identify the devices, iii. a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefore;	ADS will draw up a declaration confirming all required details and that GSPRs have been met. The declaration will be made publicly available via the ADS website
(g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and the performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;	ADS designs, develops and manufactures IVDs under ISO 13485 (Design Control) and ISO 14971 accreditation (Risk Assessment) ensuring all documentation requirements are met
(h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g);	ADS designs, develops and manufactures IVDs under ISO 13485 (Design Control) and ISO 14971 accreditation (Risk Assessment)
(i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.	ADS is ISO 13485 and ISO 15189 accredited and has- the appropriate post-production review procedures in place to ensure experience gained from clinical use of the device is reviewed and necessary corrective actions implemented