Suppliers Activities Impacting Manufacturer Regulatory Compliance (EU IVDR): *in-vitro diagnostic*

Sl. No.	REFERENCE: EU IVDR, REGULATION 2017/746	ACTIVITY/ REQUIREMENTS	DISCUSSION BETWEEN MANUFACTURER AND THEIR SUPPLIER
1.	***Article 10 General obligations of manufacturers; Section 8 (d); Page no.# L 117/197***	Manufacturer's obligation includes having a quality management system which addresses resource management, including selection and control of suppliers and sub-contractors.	
2.	***Article 88 Market surveillance activities; Section 3(b); Page no.# L 117/246***	Under Market Surveillance, the competent authorities shall carry out both announced and unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users. *NOTE: The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples. The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.*	
3.	***ANNEX II TECHNICAL DOCUMENTATION; Section 3.2(b); Page no. # L 117/272***	Manufacturer has to disclose actual identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed in their respective technical documentation	
4.	***ANNEX VII REQUIREMENTS TO BE MET BY NOTIFIED BODIES; Section 1.2.3 (a); Page no. # L 117/288***	The notified body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not: (a) be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of devices which they assess, nor the authorized representative of any of those parties. Such restriction shall not preclude the purchase and use of assessed devices that are necessary for the operations of the notified body and the conduct of the conformity assessment, or the use of such devices for personal purposes, (d) offer or provide any service which may jeopardize the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the	
5.	***ANNEX VII REQUIREMENTS TO BE MET BY NOTIFIED BODIES; Section 1.2.3 (d); Page no. # L 117/288***		

		manufacturer, its authorized representative, a supplier or a commercial competitor with regards to the design, construction, marketing or maintenance of the devices or processes under assessment.	
6.	***ANNEX VII REQUIREMENTS TO BE MET BY NOTIFIED BODIES; Section 4.5. Conformity assessment activities, Subsection 4.5.2.(a)-Point 2***	As part of the assessment of the quality management system, a notified body shall, prior to an audit and in accordance with its documented procedures: — identify links between and allocation of responsibilities among, the various manufacturing sites, and identify relevant suppliers and/or subcontractors of the manufacturer, and consider the need to specifically audit any of those suppliers or subcontractors or both, if required.	
7.	***Page no. # L 117/296 ANNEX VII REQUIREMENTS TO BE MET BY NOTIFIED BODIES; Section 4.5. Conformity assessment activities, subsection 4.5.2.(b)-Point 5*** ***Page no. # L 117/297***	Based on the audit programme it has drawn up, the notified body shall, in accordance with its documented procedures: — if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers.	
8.	***ANNEX VII REQUIREMENTS TO BE MET BY NOTIFIED BODIES; Section 4.10- Point 1, Surveillance activities and post-certification monitoring***	The notified body shall have documented procedures defining how and when surveillance activities of manufacturers are to be conducted. Those procedures shall include arrangements for unannounced on-site audits of manufacturers and, where applicable, subcontractors and suppliers carrying out product tests and the monitoring of compliance with any conditions binding manufacturers and associated with certification decisions, such as updates to clinical data at defined intervals.	
9.	***Page no. # L 117/301 Annex IX -CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESS-MENT OF TECHNICAL DOCUMENTATION, Section 2.3; Chapter-I: Quality Management System*** ***Page no. # L 117/308***	The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.	

10.	***Annex IX -CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION, Section 3.3.; Chapter-I: Quality Management System*** ***Page no. # L 117/309***	Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.	
11.	***Annex IX -CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION, Section 3.4; Chapter-I: Quality Management System;*** ***Page no. # L 117/309***	The notified body shall randomly perform, at least once every five years, unannounced audits on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.	

Reference:
REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

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