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Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746

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Relevant obligations arising from Article 16(1)

Any distributor, importer or other natural or legal person that assumes the obligations incumbent on manufacturers in accordance with Article 16(1), assumes all the relevant responsibilities related to UDI, including UDI labelling.

This means that those economic operators must also apply for registration as Manufacturers, receive a Single Registration Number (SRN), apply for the appropriate conformity assessment procedure and feed and provide UDI-product registration.

However, in accordance with the provision of Article 16(1)a, when a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label, the manufacturer is responsible for meeting the requirements placed on manufacturers in this Regulation, including the relevant UDI obligations.

Relevant obligations arising from Article 16(2) to 16(4)

The distributor or importer carrying out the operations in Article 16(2) shall ensure that:

- the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that in no way compromise the readability of the UDI carrier and its information identifying the actual device.

- the specific procedures are part of the distributor's or importer's quality management system.