Checklist for Importers

This checklist is designed to help importers check that they are complying with the requirements of the MDR and IVDR. It assumes that the importer does not make any modifications to the device that would result in additional requirements under Article 16.

# Requirements that must be met by each importer

| Requirement | Regulatory reference | Done |
| --- | --- | --- |
| SRN requested | Annex VI | [ ] |
| Registered in EUDAMED | Article 31, Annex VI | [ ] |
| Process that regulates responsibilities for ensuring that the data in EUDAMED is up-to-date defined | Article 31 | [ ] |
| Important work instructions and standard operating procedures, as mentioned below, created |  | [ ] |
| Competence of own staff determined and proven |  | [ ] |

# Requirements that must be met for each device type

| Requirement | Regulatory reference | Done |
| --- | --- | --- |
| Contract with manufacturer drawn up (delivery, communication channels, provision of own details on or with product, etc.) |  |  |
| Copy of the declaration of conformity provided | Article 13(2), Article 13(9) | [ ] |
| Confirmation that there is an authorized representative | Article 13(2) | [ ] |
| Verification that the device is registered in EUDAMED | Article 13(4) | [ ] |
| How the importer's information will be provided with the device (e.g., on the device, on the packaging, in an accompanying document) has been defined | Article 13(3) | [ ] |
| Work instructions or standard operating procedures specifying how this information will be provided (e.g., by enclosing a document, can also be done by the manufacturer) have been created | Article 13(3) | [ ] |
| Work instruction or standard operating procedure specifying how and how many devices will be inspected available | Article 13(2) | [ ] |
| Work instruction or standard operating procedure describing which parties (manufacturer, authorities, third parties) must be informed of which problems, as well as how, by which deadline and via which people, available |  |  |
| Work instruction or standard operating procedure on document control, including retention periods, created |  |  |
| Manufacturer contact and communication channel specified | Article 13(2), Article 13(7) | [ ] |
| Competent authority and communication channel determined and documented | Article 13(2), Article 13(7) | [ ] |
| Work instruction or standard operating procedure that defines how complaints, recalls and non-conforming devices are documented in the register created | Article 13(6) | [ ] |
| Register for the collection and forwarding of complaints, recalls and non-conforming devices established | Article 13(6) | [ ] |
| Storage conditions clarified with manufacturer | Article 13(5) | [ ] |
| Work instruction or standard operating procedure on how it is continuously ensured that the storage conditions are met created | Article 13(5) | [ ] |
| Work instruction or standard operating procedure and, if necessary, system specifying how device traceability will be ensured (who received or returned which device when) created. Record the UDI for this | Article 25(1) |  |

# Requirements to be met for each device

| Requirement | Regulatory reference | Done |
| --- | --- | --- |
| Verification that the device is CE marked | Article 13(2) | [ ] |
| Verification that the device is labeled in accordance with the MDR/IVDR | Article 13(2) | [ ] |
| Verification that the instructions for use (as required) are provided | Article 13(2) | [ ] |
| Verification that the device has been assigned a UDI | Article 13(2) | [ ] |
| Verification that your own labeling does not cover the manufacturer's | Article 13(3) | [ ] |

# Other information

Please contact the Johner Institut if you have any questions or would like support:

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