Johner Institut

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.

1. 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		[ ]

2. 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)	[ ]

Johner Institut GmbH
Reichenaustraße 1
78462 Konstanz
T +49 7531 94500-20
info@johner-institut.de
www.johner-institut.de

Director:
Prof. Dr. Christian Johner
HRB 710768 District Court of Freiburg

Volksbank Konstanz
IBAN: DE12 6929 1000 0228 0643 00
BIC: GENODE61RAD

Johner Institut

Requirement	Regulatory reference	Done
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)	

Johner Institut GmbH
Reichenaustraße 1
78462 Konstanz
T +49 7531 94500-20
info@johner-institut.de
www.johner-institut.de

Director:
Prof. Dr. Christian Johner
HRB 710768 District Court of Freiburg

Volksbank Konstanz
IBAN: DE12 6929 1000 0228 0643 00
BIC: GENODE61RAD

Johner Institut

3. 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:

- Email: info@johner-institut.de
- Contact form: https://www.johner-institut.de/kontakt
- Telephone: +49 (7531) 94500 20

Johner Institut GmbH
Reichenaustraße 1
78462 Konstanz
T +49 7531 94500-20
info@johner-institut.de
www.johner-institut.de

Director:
Prof. Dr. Christian Johner
HRB 710768 District Court of Freiburg

Volksbank Konstanz
IBAN: DE12 6929 1000 0228 0643 00
BIC: GENODE61RAD