

REGULATION (EU) 2017/745 · ARTICLES 10, 11, 15, 29 AND 31

EU Authorised Representative Readiness Checklist

For medical device manufacturers established outside the European Union

Article 11(1) of the MDR sets the starting point: **"Where the manufacturer of a device is not established in a Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorised representative."**

Under Article 11(3)(a) the authorised representative must **"verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;"** This checklist lists what a representative will ask to see before it accepts a mandate. Tick **Ready** where the item exists and is current, **Gap** where it does not. Every Gap is work to finish before signing.

Legislation is quoted word for word, in bold, from the consolidated text of 10 January 2025 (CELEX 02017R0745-20250110, eur-lex.europa.eu). Text in normal weight is our working note. For in vitro diagnostic devices the parallel provisions are in Regulation (EU) 2017/746.

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1. Technical documentation and declaration of conformity

Article 10(4): **"Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices." "The technical documentation shall include the elements set out in Annexes II and III."**

Art.	What to have ready	Ready	Gap
10(4)	Technical documentation structured to Annex II: device description, labelling, design and manufacturing information, general safety and performance requirements, benefit-risk analysis and risk management, verification and validation.	☐	☐
10(4)	Post-market surveillance documentation structured to Annex III.	☐	☐
10(3), 61	Clinical evaluation report, current, covering every claim made in the labelling and promotional material.	☐	☐
10(6)	EU declaration of conformity signed. Article 19(1): "The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV"	☐	☐
10(6)	Conformity assessment route identified for each device class; notified body certificate where the route requires one.	☐	☐
10(8)	Retention arranged: "for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market." Implantable devices: "at least 15 years after the last device has been placed on the market."	☐	☐
10(8)	A way for the representative to hold the file. The manufacturer must "ensure that the authorised representative has the necessary documentation permanently available."	☐	☐

2. Quality management and post-market surveillance

Article 10(9): **"Manufacturers of devices, other than investigational devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device."**

Art.	What to have ready	Ready	Gap
10(9)	Quality management system covering at least the aspects listed in Article 10(9), points (a) to (m), including the strategy for regulatory compliance.	☐	☐
10(9)	Procedures that keep series production in conformity and handle design changes and changes in standards.	☐	☐
83(1)	Post-market surveillance system per device. "That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9)."	☐	☐
84, 85, 86	Post-market surveillance plan, and a post-market surveillance report (class I) or periodic safety update report (class IIa, IIb, III).	☐	☐

3. Person responsible for regulatory compliance

Article 15(1): **"Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices."**

Art.	What to have ready	Ready	Gap
15(1)	Named person with evidence of either qualification route in Article 15(1)(a) or (b).	☐	☐
15(2)	Micro or small enterprise: "shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal." Written arrangement in place.	☐	☐
15(3)	Responsibilities assigned in writing, covering release checks, technical documentation, post-market surveillance and vigilance reporting.	☐	☐
15(6)	Note: the representative needs its own. "Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union."	☐	☐

4. UDI and EUDAMED registration

Article 10(7): **"Manufacturers shall comply with the obligations relating to the UDI system referred to in Article 27 and with the registration obligations referred to in Articles 29 and 31."**

Art.	What to have ready	Ready	Gap
31(1)	Actor data ready for registration. "Before placing a device, other than a custom-made device, on the market, manufacturers, authorised representatives and importers shall, in order to register, submit to the electronic system referred to in Article 30 the information referred to in Section 1 of Part A of Annex VI"	☐	☐
31(1)	Where a notified body is involved, actor registration done "before applying to the notified body."	☐	☐
27(3)	Account with an issuing entity designated by the Commission and a UDI assigned to each device and higher packaging level.	☐	☐
29(1)	Basic UDI-DI assigned per device group, with the core data elements of Annex VI Part B ready for the UDI database.	☐	☐
11(3)(c)	The representative will "comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29;"	☐	☐

5. Labelling and language

Annex I, Section 23.2(d): the label shall bear **"if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;"**

Art.	What to have ready	Ready	Gap
Annex I 23.2(d)	Label artwork with a field reserved for the representative's name and address.	☐	☐
10(11)	Translations planned. "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient."	☐	☐
19(1)	Declaration of conformity "translated into an official Union language or languages required by the Member State(s) in which the device is made available."	☐	☐

6. Vigilance, corrective action and liability

Article 10(13): **"Manufacturers shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88."**

Art.	What to have ready	Ready	Gap
10(13)	Vigilance procedure with reporting timelines, and a contact route from the representative for complaints it receives under Article 11(3)(g).	☐	☐
10(12)	Procedure for corrective action, withdrawal and recall that informs "the distributors of the device in question and, where applicable, the authorised representative and importers accordingly."	☐	☐
10(14)	Ability to supply samples or device access to a competent authority on request.	☐	☐
10(16)	Manufacturers shall, "in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC"	☐	☐
11(5)	Awareness of the representative's position: where the manufacturer "has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer."	☐	☐

7. The mandate itself

Article 11(2): **"The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group."**

Art.	What to have ready	Ready	Gap
11(2)	List of devices and generic device groups to be covered, with Basic UDI-Dis.	☐	☐
11(3)	Draft mandate containing at least the eight tasks in Article 11(3)(a) to (h). Our separate mandate checklist walks through each clause.	☐	☐
11(4)	No clause that delegates the obligations in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12).	☐	☐
12	Changing representative: a transfer agreement covering at least the four aspects in Article 12(a) to (d).	☐	☐

Next step

Medex Kurumsal Danışmanlık acts as EU authorised representative for manufacturers outside the Union, EUDAMED SRN TR-AR-000057550. Send us this checklist with your Gap items marked and we will tell you what has to be completed before a mandate can be signed. We are not a law firm and this checklist is not legal advice.

www.medexeurep.com/request-a-proposal

Related guides: EU authorised representative (medexeurep.com/eu-rep/eu-authorized-representative) · MDR Article 11 (medexeurep.com/post/mdr-article-11) · Technical documentation (medexeurep.com/post/technical-documentation) · EU REP FAQ (medexeurep.com/eu-authorized-representative-faq). Guidance: MDCG 2022-16 on authorised representatives, health.ec.europa.eu.