

EU Authorised Representative Mandate Checklist

Use this list to check a draft mandate against Regulation (EU) 2017/745. The task wording in the tables is quoted from the consolidated text of 10 January 2025. Write the clause number of your draft next to each item; an empty cell is a gap to close before signing. The same tasks apply under Article 11 of Regulation (EU) 2017/746 for IVDs.

1. Form and scope (Article 11(1) and (2))

Art.	Requirement	Clause no.	OK
11(1)	A manufacturer not established in a Member State designates a sole authorised representative. One representative, not one per country.		
11(2)	The mandate is valid only when accepted in writing by the authorised representative.		
11(2)	It covers at least all devices of the same generic device group. List the groups and Basic UDI-DIs in an annex.		
11(3)	The authorised representative provides a copy of the mandate to the competent authority on request.		

2. Minimum tasks the mandate must require (Article 11(3))

"The mandate shall require, and the manufacturer shall enable, the authorised representative to perform at least the following tasks in relation to the devices that it covers:"

Art.	Task (quoted)	Clause no.	OK
11(3)(a)	"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"		
11(3)(b)	"keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8)"		
11(3)(c)	"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"		
11(3)(d)	"in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned"		
11(3)(e)	"forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device"		
11(3)(f)	"cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices"		
11(3)(g)	"immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated"		
11(3)(h)	"terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation"		

3. What the mandate cannot do (Article 11(4) to (6))

Art.	Requirement	Clause no.	OK
11(4)	The mandate may not delegate the manufacturer's obligations in Article 10(1), (2), (3), (4), (6), (7), (9), (10), (11) and (12). Check that no clause shifts them to the representative.		
11(5)	Where the manufacturer has not complied with Article 10, the authorised representative is liable for defective devices jointly and severally with the manufacturer. Check the insurance and indemnity clauses.		
11(6)	A representative that terminates under 11(3)(h) must immediately inform its competent authority and, where applicable, the notified body. Check the notice procedure.		

4. Changing representative (Article 12)

The agreement between the manufacturer, where practicable the outgoing representative, and the incoming representative "shall address at least the following aspects":

Art.	Aspect (quoted)	Clause no.	OK
12(a)	"the date of termination of the mandate of the outgoing authorised representative and date of beginning of the mandate of the incoming authorised representative"		
12(b)	"the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material"		
12(c)	"the transfer of documents, including confidentiality aspects and property rights"		
12(d)	"the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or incoming authorised representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which it had been designated as authorised representative"		

Source: Regulation (EU) 2017/745, consolidated text of 10 January 2025, eur-lex.europa.eu (CELEX 02017R0745-20250110). Guidance: MDCG 2022-16 on authorised representatives. This checklist is a working aid, not legal advice.

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