Ministry of Health, Welfare and Sport

Authorised representatives of medical devices do not always meet the basic requirements

The Dutch Health and Youth Care Inspectorate (IGJ) supervises authorised representatives based in the Netherlands of medical devices manufacturers. In 2022-2023, the IGJ inspected 24 authorised representatives acting on behalf of more than three manufacturers in relation to specified tasks with regard to the latter's obligations under the MDR/IVDR. This publication aims to inform readers about the results of these inspections carried out. The IGJ outlined specific actions for improvement for all authorised representatives in order to contribute to safe and effective medical devices in the European Union in accordance with the requirements of the MDR/IVDR.

What are authorised representatives and why is this supervision important?

Where a manufacturer of a medical device is not established in a European Member State, the medical device may only be placed on the Union market if the manufacturer designates a sole authorised representative. The authorised representative has a crucial role in marketing a safe and effective medical device that is produced by the manufacturer outside the EU and acts as the manufacturer's legal representative. The tasks and responsibilities of the authorised representative are specified in a written mandate between the authorised representative and the manufacturer. The authorised representative is responsible for representing the manufacturer and falls under the supervision of the inspectorate in the EU Member State where the authorised representative is located. European Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) set out the legal requirements that authorised representative have to meet.

The authorised representative acts as the gateway to the entire European market for any non-EU manufacturer. Authorised representatives have the important tasks and responsibilities to ensure that the medical device complies with applicable regulatory requirements. Authorised representatives are also involved in carrying out adequate market surveillance and in issuing any safety warnings or carrying out product recalls when necessary. In short, authorised representatives are an essential link in the chain of ensuring safe and effective medical devices across the EU.

Medical devices that are placed on the European market from outside the EU include all device groups, from band-aids to implants. These devices include devices classified in accordance with the requirements of the Regulations as low and high risk. A single authorised representative may represent an unlimited number of manufacturers and medical devices. As a result, the number of medical devices placed on the European market or put into service through the intervention of a single authorised representative can be significant. Some authorised representatives represent more than 50,000 medical devices. Inspectorates within the EU do not have direct supervision over the original manufacturers outside the EU, which stresses the important of the supervision of authorised representatives.

Glossary of common terms

The term 'medical device' in this publication includes medical devices, accessories for medical devices, products listed in Annex XVI of the MDR, in vitro diagnostic medical devices, accessories for in vitro diagnostic medical devices and also custom-made devices (MDCG 2022-16).
Definition of an authorised representative: any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation (MDR Article 2(32) and IVDR Article 2 (25)).

PRRC stands for Person Responsible for Regulatory Compliance. This person is responsible for ensuring compliance with the relevant legislation and Regulations within the organisation of a manufacturer and that of an authorised representative.

The IGJ aims to achieve better compliance with the requirements of the MDR/IVDR on the part of authorised representatives through this publication. The key areas of improvement for authorised representatives are:

- The scope of tasks must not be limited to the minimum legal requirements. Their activities must be carried out in a manner that is appropriate to the key role that an authorised representative accepted in ensuring the safety of medical devices.
- Internal processes must be tightened to maximise their contribution in order to place safe and effective medical devices on the market.
- Agreements with the manufacturer(s) must be laid down in (more) detail. The device group(s) for which the authorised representative is responsible shall, for example, always be laid down in writing.
- Ensure that the legal authorised representative is clearly registered for all device groups.
- Ensure that at least one PRRC is located in an EU Member State. Ensure that the PRRC meets the legal requirements with regard to level of education and professional work experience in advance of their appointment. It must also be ensured that the PRRC has sufficient skills to properly apply the required knowledge in practice.
- The legal documentation and technical documentation shall be verified for all devices and that verification must be documented in a demonstrable manner.

Why carry out supervision on authorised representatives in the Netherlands?

Supervision of authorised representatives based in the Netherlands was initiated due to the entry into force and application of the Europeans legislation and Regulations:

- the (EU) 2017/745 Medical Device Regulation (MDR), in May 2021
- and the (EU) 2017/746 In Vitro Diagnostic Medical Devices Regulation (IVDR), in May 2022

Compared to previous Directives 93/42/EEC (MDD), 90/385/EEC (AIMDD) and Directive 98/79/EC (IVDD), both Regulations impose additional requirements on authorised representatives.

In addition, the IGJ identified a significant increase in the number of authorised representatives registered in the Netherlands (see Table 1 and 2) since 2019. In 2019, 170 authorised representatives were located in the Netherlands, which number increased to 347 in 2022. This doubling of the number of registered authorised representatives based in the Netherlands is due in part to:

- The COVID-19 pandemic: as a result of the pandemic, COVID-19-related devices were needed in a very short period of time. This led to an increase in the number of manufacturers outside the EU and with it the number of authorised representatives.
- The Brexit: authorised representatives previously located in the United Kingdom were forced to change their location to a country within the EU after the Brexit. In addition, as a result of the Brexit, manufacturers in the United Kingdom are required to designate an authorised representative within an EU Member State.

Table 1: Distribution of authorised representatives based in the Netherlands in 2019, in table and graph.

Number of manufacturers (F) represented by the authorised representative	Number of registered authorised representatives from notification systems*
F >10	7
3 ≤ F ≤ 10	14
F ≤ 2	126
Unknown	23
Total	**170**

* *The number of registered authorised representatives in 2019 came from the Notis notification system and from IGJ's own systems. Notis lists 1) manufacturers and authorised representatives based in the Netherlands who have placed a medical device (class I), a custom-made medical device or an IVD (all risk classes) on the European market, and 2) Manufacturers and authorised representatives who wish to place a CE certified medical device/IVD of a higher class on the market outside the EU and have applied for an export declaration in the Netherlands to do so.*

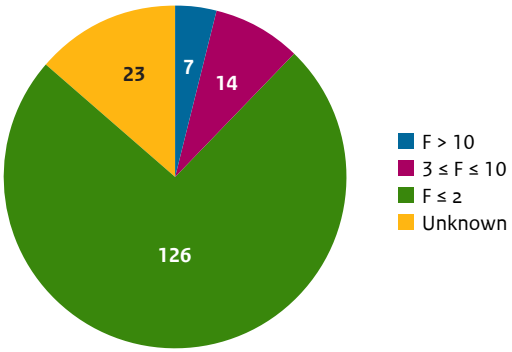
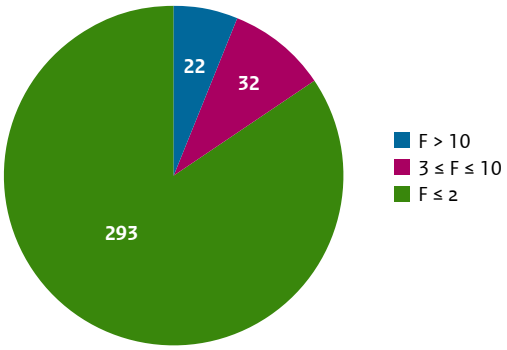


Table 2: Distribution of authorised representatives based in the Netherlands in 2022, in table and graph.

Number of manufacturers (F) represented by the authorised representative	Number of registered authorised representatives from notification systems**
F >10	22
3 ≤ F ≤ 10	32
F ≤ 2	293
Total	**347**

** *In 2022, the number of registered authorised representatives came from the notification systems Notis and EUDAMED. In EUDAMED, manufacturers, authorised representatives, importers and compilers of systems and treatment packages must register data about themselves, the company and the medical device.*



The inspectorate also observed a significant increase between 2019 and 2022 in the number of notifications involving an authorised representative based in the Netherlands. These included incident notifications and notifications from inspectorates from other EU Member States.

Supervision framework and focus

Between November 2022 and September 2023, the IGJ inspected 24 authorised representatives located in the Netherlands. The selection of these 24 authorised representatives was based on the criterium that the authorised representative represents 3 or more manufacturers of medical devices based outside of the EU under the MDR/IVDR.

Given that the MDR/IVDR have only recently been implemented, only the basic requirements for authorised representatives were assessed during these 24 inspections. These basic requirements were divided into 3 key themes, which are set out in the assessment framework for authorised representatives.

The IGJ focused its supervision on the following 3 themes:

1. The mandate between the authorised representative and the manufacturer outside of the EU
2. The knowledge and experience of the PRRC of the authorised representative
3. The responsibilities of the authorised representative in respect of the manufacturers they represent and in respect of the medical devices that are placed onto the European market by those manufacturers

IGJ concerns

General picture
During the inspections, the IGJ observed that too many authorised representatives considered the fulfilment of legal requirements as being minimum administrative requirements. The IGJ identified several examples of this, such as:

- Several sites that were inspected on site appeared to be postal addresses without any employees present. The principal place of business of the authorised representative was mostly located outside the EU, where the work likewise was primarily carried out.
- All PRRCs formally met the legal requirements in respect of education and experience as set out in the MDR/IVDR. However, in practice, it often occurred insufficient for adequate performance of the tasks of the PRRC.
- In the case of authorised representatives at which only one person was employed, this person also held the position of PRRC. In these cases, it was often not specified what the consequences would be if this person were to fall away.
- The IGJ identified several minimally performed verifications, in which the authorised representative did have the required documentation. However, it could not be established whether the authorised representatives actually verified whether those documents were correct. As a result, it was uncertain whether the medical devices demonstrably met the legal requirements and were therefore effective and safe.

The IGJ is concerned by the limited fulfilment of the scope of tasks by a number of authorised representatives. Due to the foregoing findings, the IGJ is urging authorised representatives to take the tasks and responsibilities assigned to them in the Regulations more seriously. In line with the crucial role that authorised representatives play in ensuring the safety of medical devices. Manufacturers likewise should play a crucial role in this regard. After all, they are the ones who select the authorised representative and lay down the mutual agreements in the mandate. Manufacturers and authorised representatives are jointly legally responsible for meeting the legal requirements for medical devices. Manufacturers of medical devices located outside of the EU therefore stand to benefit from an authorised representative who performs their duties to the best of their ability, thereby ensuring the safety and quality of the products.

Specific non-conformities
In addition to the overall picture outlined above, the inspectorate identified non-conformities of the requirements of the MDR/IVDR from too many authorised representatives. The IGJ inspected the authorised representatives on a number of basic requirements under the MDR/IVDR. These basic requirements chiefly relate to how authorised representatives have organised their processes, such as demonstrably verifying that the legal and technical documentation has been prepared.

In practice, these procedural non-conformities may have major consequences and risks, given that they impact all medical devices represented by the authorised representative.

Non-conformities of the basic requirements were found in more than a third of the authorised representatives inspected, i.e. 9 out of a total of 24. Some cases related to a single non-conformity, however there were equally authorised representatives at which several identified non-conformities. The IGJ raised and shared these non-conformities with the 9 authorised representatives during the inspection. A number of authorised representatives corrected the non-conformities immediately following the inspection, halting further follow-up action by the IGJ. In the cases where the authorised representatives did not immediately corrected the non-conformities, the IGJ issued a warning or imposed a fine. The IGJ expects the authorised representatives to correct all non-conformities within a reasonable period of time and will continue to monitor compliance in that regard.

Next steps
The recommendations from this publication are relevant to all authorised representatives, both within the Netherlands and in other EU Member States. The IGJ therefore aims to ensure that, where appropriate, all authorised representatives in the EU will implement these recommendations in practice.

In 2024, the IGJ will be intensifying its supervision of authorised representatives based in the Netherlands. In doing so, the inspections will no longer limit itself to the basic requirements for the mandate, PRRC and responsibilities of the authorised representative.

Please find more information about what the IGJ assessed for each key theme and IGJ's findings below.

Theme 1: the mandate between the authorised representative and the manufacturer

Theme 2: the knowledge and experience of the Person Responsible for Regulatory Compliance (PRRC) of the authorised representative

Theme 3: the responsibilities of the authorised representative in respect of the manufacturers they represent

Theme 1: the mandate between the authorised representative and the manufacturer

Aspects assessed by the IGJ:

In relation to the mandate, the IGJ assessed the requirements set out in Article 11, paragraphs 1 to 4, of the MDR/IVDR. The key requirements are that the mandate shall have been accepted in writing by the authorised representative. All medical devices covered by the mandate shall be set out in the mandate.
The authorised representative shall be in possession(a copy) of the mandate and the mandate shall set out the specific tasks and responsibilities that the authorised representative carries out on behalf of the manufacturer, as set out in the MDR/IVDR. This is essential because authorised representatives play a crucial role in ensuring that medical devices meet the regulatory requirements, for which authorised representatives are jointly responsible and legally liable alongside the manufacturer.

The full set of requirements that the IGJ assessed are set out in Theme 1 Mandate of the Assessment Framework.

At the inspections of authorised representatives based in the Netherlands, the IGJ examined at least 3 mandates with manufacturers outside of the EU under the MDR/IVDR.

What is going well?

- 16 of the 24 authorised representatives used templates to set up the mandates. The use of a correctly drafted template reduces the risk of errors when entering into a mandate with a new manufacturer.
- In all assessed mandates, the manufacturer's obligations are not delegated to the authorised representative.
  The MDR/IVDR impose various requirements on the manufacturer and the authorised representative regarding the marketing of medical devices. The manufacturer is not permitted to delegate its obligations to the authorised representative.

What has to be improved?

- Authorised representatives shall have (a copy of) the mandate available.
- The mandate shall be signed by the manufacturer and the authorised representative by a person with demonstrable authority to sign.
- The mandate shall specify the device/device groups to which the mandate applies.

What can be improved?

It would be beneficial to a large number of authorised representatives to have a better understanding and overview of all manufacturers and medical devices they represent. In fact, the IGJ too often found that authorised representatives were using different overviews/working methods. As a result it was not possible to clearly determine which medical devices from which manufacturer their activities related to. Correct document and version management makes it immediately clear which changes and/or additions have taken place to the mandate and what the most recent version is.

A number of authorised representatives are a subsidiary of a manufacturer. In those cases, they only represent that manufacturer or the manufacturers that fall under the same larger organisation, which is why they often do not specifically refer to the device/device groups in the mandate. They subsequently indicate that the mandate covers all medical devices of that manufacturer. Given that the authorised representative and the manufacturer in these cases are part of the same organisation, the IGJ concluded that there was no violation. However, it is vital in this context that the authorised representative and the manufacturer lay down their mutual agreements properly and clearly in the mandate and that the authorised representative has its own PRRC. This ensures that the authorised representative can fulfil its responsibility for the safety of medical devices on the European market.

Good examples

- One authorised representative had direct access to the manufacturer's ICT system, where all the medical devices for which they were responsible were immediately visible. As a result, the list is always up to date and the mandate does not need to be amended in the event of updates. The mandate contained a clear reference to this ICT system;
- Where the mandate was already in force before the MDR/IVDR came into effect, one authorised representative relied on an amendment from a previous contract already established between the manufacturer and the authorised representative. This made it clear which medical devices were represented by the authorised representative under the MDR/IVDR and which fell under the MDD/IVDD.

Theme 2: the knowledge and experience of the Person Responsible for Regulatory Compliance (PRRC) of the authorised representative

Aspects assessed by the IGJ:

In relation to the PRRC, the IGJ assessed the requirements outlined in Article 15, paragraph 6 (a) and (b) of the MDR/IVDR. The key requirements are that the authorised representative shall designate at least one person in charge of compliance with the legislation and Regulations governing medical devices. This person shall have the necessary qualifications and relevant professional work experience and shall be able to provide evidence of this. In addition the MDCG 2019-7 provides an additional requirement that the PRRC must be located in an EU Member State.

The full set of requirements that the IGJ assessed are set out in Theme 2 Knowledge and skills of the Assessment Framework.

What is going well?

- All 24 authorised representatives that were inspected had appointed at least one person as the PRRC in charge of ensuring compliance with the legislation and Regulations governing medical devices at the time of the inspection.
- All 24 authorised representatives were able to provide evidence that the appointed PRRC met the education and qualification requirements for PRRCs.

What has to be improved?

- The PRRC shall already meet the legal requirements for the PRRC at the start of the appointment, meaning that the required professional work experience cannot be gained solely during the appointment.
- In addition to the legal requirements, the PRRC must also have sufficient skills to be able to apply that knowledge appropriately in practice.
- At least one PRRC must be located in an EU Member State.

What can be improved?

The legislation states that at least one PRRC must be appointed who is responsible for ensuring compliance with legislation and Regulations. Not all PRRCs were able to execute their tasks and responsibilities sufficiently independently of the director. Although not formally required, this ensures that compliance with legislation and Regulations is given adequate attention by the authorised representative. As a rule, authorised representatives do not weigh up whether that responsibility could be assigned to one or more PRRCs. In the case of authorised representatives who represent a large number of manufacturers and medical devices, the IGJ expects them to have substantiated how many PRRCs are needed to perform their tasks effectively. The IGJ also believes it is important that they have ensured that one PRRC is always available. Furthermore, several authorised representatives did not have a clear remit and/or job description for the role and responsibilities of the PRRC. A clear definition of the relevant tasks and responsibilities is appropriate considering the important role played by a PRRC.

Good examples

- Several authorised representatives had a number of employees that met the education and qualification requirements for PRRCs. As a result, in the event of the absence of one PRRC, there is sufficient assurance that this role can be taken over by another employee within the company.
- A number of authorised representatives were able to thoroughly demonstrate the added value of their PRRCs, for example, due to the fact that the PRRC was involved in the exchange of data with manufacturers and in the verification of documents required by law.

Theme 3: Responsibilities of the authorised representative in respect of the manufacturers they represent

Aspects assessed by the IGJ:

In relation to the responsibilities of the authorised representative, the IGJ assessed the requirements set out in Article 11, paragraph 3 (a) to (h) of the MDR/IVDR. The key requirements in this context are that authorised representatives shall be able to demonstrate that they have verified that the technical documentation and the EU declaration of conformity have been drawn up, and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer.

In addition, the authorised representative shall be in possession of (a copy of) the most recent technical documentation, the EU declaration of conformity and, if applicable, the CE certificate. The authorised representative shall also comply with the registration requirements for authorised representatives. It shall also verify whether the manufacturer has fulfilled its registration obligations. The authorised representative shall have defined criteria under which the mandate can be determined. All this ensures that the authorised representative can properly exercise its pivotal role in ensuring the conformity of medical devices produced by manufacturers.

The full set of requirements assessed by the IGJ are set out under Theme 3 Responsibilities of the Assessment Framework.

What is going well?

- Most authorised representatives had defined criteria for the termination of the mandate with the manufacturer. This allows authorised representatives to prevent a medical device from being placed on the European market, if the legal requirements are no longer met.
- 22 of the 24 authorised representatives were able to demonstrate (a copy of) the technical documentation, the EU declaration of conformity and, if applicable, a CE certificate of the requested devices, during the inspection.

What has to be improved?

- Authorised representatives shall record and be able to demonstrate that they have verified that the technical documentation and the EU declaration of conformity have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer.
- Authorised representatives shall address manufacturers to account if they have identified multiple authorised representatives listed in the European registration system EUDAMED for the same device (group). This is because in a situation where a device poses a (potential) risk to patient safety, it should immediately be clear who the legal representative is.

What can be improved?

The IGJ expects authorised representatives themselves to take more of an active role in verifying required documentation. This means that they must also actively verify whether the medical devices may still be placed on the market in under the relevant legislation and Regulations at times other than when asked by the manufacturer. In addition, authorised representatives had not always documented the consequences of terminating a mandate. Upon termination of the mandate, inter alia the medical device may no longer be placed on the European market by the manufacturer.

Good example

- Three authorised representatives made use of an ICT system in which the entire verification process was carried out. In this context, the manufacturer is responsible for ensuring that the correct information/documentation is provided, after which the authorised representative must verify this information/documentation. Only then is the importer allowed to carry out the checks. This makes the release process fully dependent on all necessary controls.