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Article 16(4) Certification Medical Devices and IVDs

Frequently asked questions

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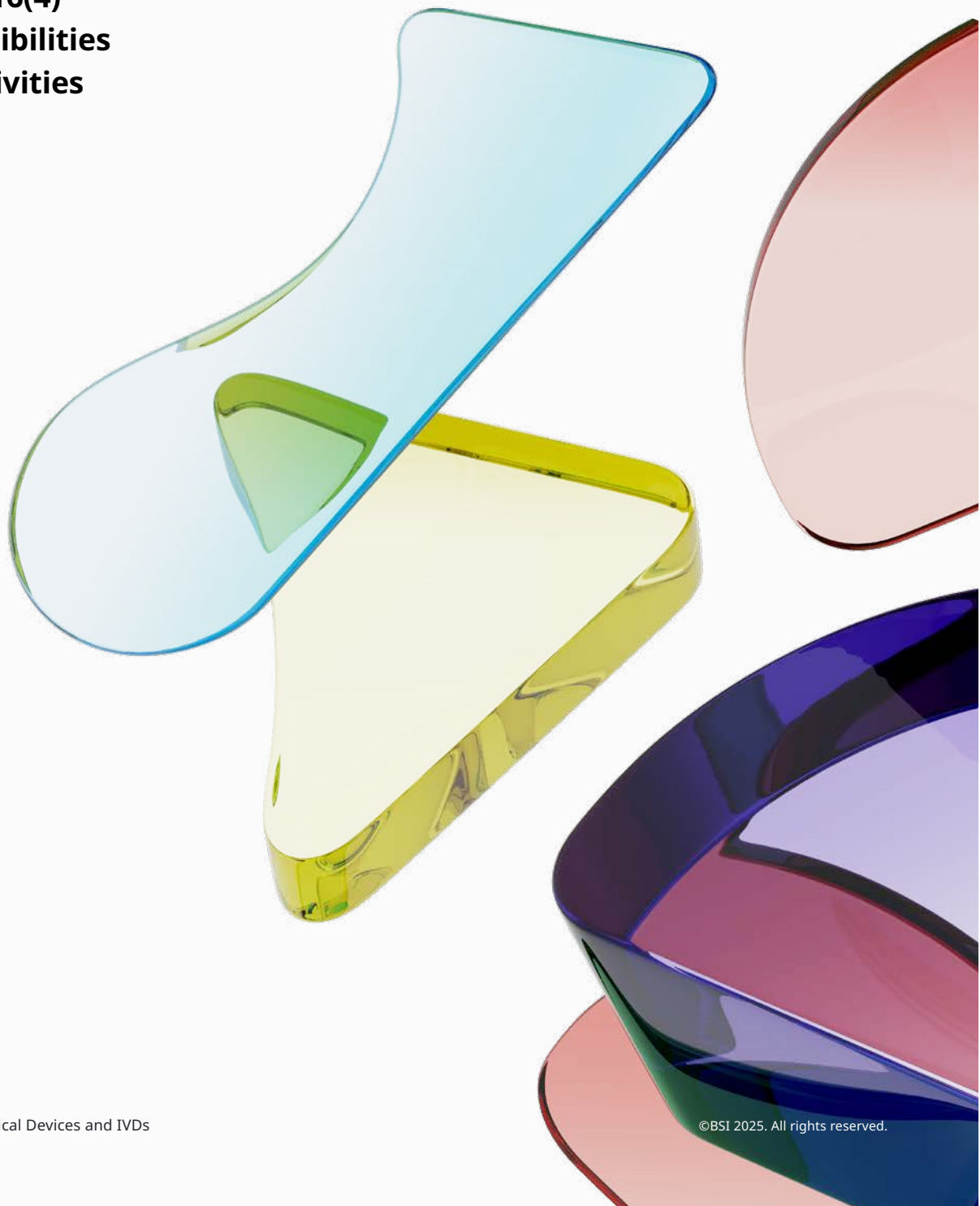

Introduction

What is Article 16(2, 3, 4)?

Article 16(3) of EU-MDR/EU-IVDR introduces requirements related to the quality management system (QMS) to be established by importers/ distributors (I/D) carrying out relabelling and/or repackaging activities (as defined in Article 16(2) on devices that have already been placed on the EU/EEA market. The relabelling and/or repackaging activities are required to meet the local requirements of EU member States where the device will be made available. Under Article 16(2, 3, 4) these activities are considered not to affect the compliance of the devices with the applicable requirements.

Article 16(2) activities conducted under an established QMS shall be audited by an MDR/ IVDR designated Notified Body. Following a successful audit, the Notified Body will issue an MDR Article 16(4) Certificate and/or an IVDR Article 16(4) Certificate.

Article 16(4) of MDR/IVDR requires that I/D who undertake relabelling and/or repackaging activities under an established QMS obtain a certificate from a Notified Body attesting that the established QMS complies with the requirements specified in Article 16(3) for the activities described in Article 16(2).

I/D shall submit the MDR/IVDR Article 16(4) certificate(s) to the Competent Authorities of the EU Member States in which they plan to make the modified devices available.

To whom is Article 16(2, 3, 4) relevant and why is Article 16(4) certification necessary?

Several parallel traders modify products to meet national regulatory requirements without informing the Legal Manufacturer on their relabelling/ repackaging activities. Often, Legal Manufacturers (LM) pursue legal action against parallel traders. The EU's Court of Justice ruled in several cases that I/D are allowed to relabel/repackage devices that are already placed on the EU market making them available in the EU member States. According to the Court of Justice, the devices continue to comply with the General Safety and Performance Requirements (GSPR) of Annex I of MDR/IVDR and have already passed the Conformity Assessment and Certification Process, as done by the Legal Manufacturer. As consequence, these relabelling/ repackaging changes do not impact device compliance with the applicable requirements and can therefore be implemented and made available by I/D without requiring additional Conformity Assessment activities.

As pointed out in the recitals (whereas) MDR #38 and IVDR #36, parallel trade in products already placed on the market is a lawful form of trade. However, the application of the principle of parallel trade is subject to different interpretations in the Member States. Considering the case-law of the EU Court of Justice and the existing good practice in the field of medical devices, Regulations have been issued to specify the conditions, in particular the requirements for relabelling and repackaging.

- Article 16(1) of MDR/IVDR Regulations now specifies in which cases the I/D who modify devices shall assume the obligations of the Legal Manufacturer and meet the requirements of Article 10 MDR/IVDR.
- Article 16(2) describes the situations where the obligations of the Legal Manufacturer as defined in Article 10 do not apply to I/D. I/D conducting relabelling and/or repackaging activities as described in Art 16(2) shall meet Article 16(3) requirements and obtain an Article 16(4) Certificate from an MDR/IVDR designated Notified Body following a successful Conformity Assessment Audit.

MDR/IVDR Article 16(2, 3, 4) allow I/D to conduct Article 16(2) activities (relabelling/repackaging) on devices already placed on the EU/EEA market under a certified QMS containing procedures aimed at ensuring that these activities will not affect the original conditions of the device.

In line with the Treaty on the Functioning of the European Union (TFEU Article 34-36) and the European's New Legislative Framework as described in EU's "Blue Guide on the Implementation of the product rules", allowing I/D to modify devices and make them available, will:

- Stimulate device availability which serves the protection of health and safety.
- Stimulate free trade within the EU.
- Promote competition.

Allowing importers and distributors to modify devices under prescribed conditions under a Notified Body certified QMS and making them available will ensure compliance of devices with the local requirements, which would not be met by devices from the Legal Manufacturer. Article 16(3) and MDCG 2021-23 describe the requirements the QMS shall meet. Examples of additional Local Requirements are given in MDCG 2021-23 (e.g., additional mandatory information, adding translations, or a specific number of devices in a box, which could prevent small hospitals from purchasing a box with too many devices).

Article 16(2, 3, 4) specifically addresses the obligations of I/D operating in the EU market, in regard of devices already placed on the market under MDR or IVDR and engaging in the specific relabelling/repackaging activities described in Article 16(2) of the MDR/IVDR.

Article 16(4) Certification is necessary because it ensures that devices already placed on the Union market, subsequently modified by I/D (including entities acting in parallel trade) and made available, continue to meet the regulatory requirements of the MDR/IVDR. Article 16(4) Certification confirms that these devices comply with the QMS requirements as defined in Article 16(3). Article 16(4) Certification enhances:

- Transparency and accountability in the supply chain.
- Safeguarding of public health.
- Trust in the quality and safety of the devices available on the market.

For whom Article 16(4) certification is not relevant?

Article 16(4) certification is not required for:

- I/D who are subcontracted by Legal Manufacturers to perform relabelling or repackaging under the manufacturer's control.
- A health institution or hospital that splits up a large pack of devices, which they have received, into smaller pack sizes or individual units for use or circulation within the health institution/hospital.
- I/Ds conducting relabelling/repackaging activities on Legacy Devices (which are under Directive Certification).

The Article 16(4) Certification process

What is the process to obtain an Article 16(4) Certification?

Article 16(4) Certification will increase transparency and accountability in the supply chain by enhancing transparency for Legal Manufacturers (LM) and Competent Authority(ies) (CA) of the Member State(s). Under this framework, importers/ distributors (including parallel traders) shall:

- Inform the Legal Manufacturer(s) and the Competent Authorities at least 28 days prior to making the relabelled or repackaged devices available on the market of the intention to make the relabelled or repackaged device available. Subsequently, the LM and CA can take appropriate actions. Upon request the I/D shall provide the LM and CA with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.
- I/D shall set up a contract agreement with the Legal Manufacturer the I/D is purchasing the device from. To respond to safety issues or to bring the device into conformity with regulation, the Legal Manufacturer should ensure that the I/D is informed in a timely manner of any corrective action taken by the manufacturer in relation to the device in question. See also LM obligations Article 10(12) and the obligations in Article 13 (Importers) and Article 14 (Distributors).
- After the LM is informed on the modifications on the devices applied by the I/D, the LM can evaluate the changes (meet/not meet the Art 16(3) requirements) and can include the modified devices in their post market surveillance plans. LM shall inform I/D in case of any corrective actions taken by the manufacturer to bring its nonconforming devices back into conformity. See LM obligations in Article 10(12).

- CA evaluates the devices (compliant/not compliant) with national legislative requirements and start their surveillance.
- The I/D obtains an Article 16(4) Certificate from a Notified Body designated for the type of devices that are subject to activities mentioned in Article 16(2), attesting that the QMS of the I/D complies with the requirements laid down in Article 16(3).
- I/D shall hold a contract agreement with a Notified Body's Article 16(4) Certification Scheme which should specify the possibility for the Notified Body to perform on-site QMS audits against Article 16(3) requirements at the premises of the I/D or their subcontractors, if needed/applicable. The QMS requirements are specified in more detail in **MDCG 2021-23**.
- Within the 28 days period prior to making the device available, the I/D shall submit the Article 16(4) Certificate to the Competent Authority of the EU Member States where they intend to distribute the devices. CAs have the authority to request product samples, allowing for improved market surveillance and regulatory oversight.

Article 16(4) responsibilities and activities

In case I/Ds are performing relabelling/ repackaging activities outside of LMs control, are they responsible for applying to obtain an Article 16(4) Certification?

Yes. However, the below cases need to be considered:

- **LM Distribution Centres:** LMs collaborate with their own distribution centres or with independent distribution centres that operate under their own ISO 13485 QMS rather than the LM's QMS. These distribution centres must comply with MDR/IVDR requirements and therefore require Article 16(4) Certificate rather than an ISO accredited certificate to implement the changes and making the devices available on the EU Market. For example, a manufacturer may seek an Article 16(4) Certification to market single pack rather than multi-pack devices in particular countries.
- **I/D (e.g., parallel trader) under Directives:** under the directives there were no requirements for I/D (e.g., parallel trader) who relabelled/repackaged devices to inform the LM on their activities. Multiple legal cases were initiated by LMs who disagreed with the modifications implemented by I/D (see MDR Whereas #38 / IVDR #36). LMs claimed their intellectual property rights and argued that the modifications could lead to a loss of reputation from incorrect translations or untidy packaging. In some cases, the EU court ruled in favour of the LM and in others, the Court ruled in favour of the I/D. After the MDR and IVDR came in effect, the directive devices (i.e., legacy devices certified under the Directive Certificates) can continue to be relabelled/repackaged and made available in the EU/Member States without an Article 16(4) Certificate.
- **I/D (e.g., parallel trader) under Regulations:** under Article 16 (2, 3, 4) of the MDR/IVDR, I/D (e.g., parallel traders) who conduct Article 16(2) activities on MDR/IVDR certified devices shall inform the LM on their intention to market these devices after implementing modifications as described in Article 16(2). The LM shall be notified at least 28 days upfront on the intention to relabel and/or repackage the devices and make these devices available in particular EU-Member States. Upon LM request, the I/D shall provide the LM with a sample or mock-up (including all labelling) of the modified device to evaluate the modifications. LM approval is not required for I/D conducting Article 16(2) activities.

What constitutes relabelling or repackaging?

Repackaging and relabelling activities include any modifications or additions made to the packaging or labelling of a medical device, without altering the device's original condition. Specific activities include:

- Translating information provided by the manufacturer (e.g., Instructions for Use to meet national language requirements.
- Adding additional information to packaging or labelling to comply with national regulatory requirements (e.g., warnings, instructions, or regulatory marks).
- Repackaging devices without altering their original condition because of the need to supply the device in a new package with different configurations, a specific number of devices different from the number of devices supplied in the original packaging by the manufacturer, for reasons of:
  - Changing the pack size (i.e., providing the healthcare system with pack sizes that are suitable for the needs of health institutions in that Member State).
  - National practices authorising only a certain packaging size.
  - Health insurance rules making the reimbursement of medical expenses dependent on the size of the packaging.
  - Well-established medical prescription practices.
  - Change from multipack (multiple devices in one package) to single pack or vice versa.
- Changing outer-packaging materials or design to adapt to local market or distribution needs, ensuring it aligns with national regulatory requirements.

As pointed out in Art 16(3), an importer or distributor that carries out any of the activities mentioned in Article 16(2) shall indicate on the device or, where that is impracticable, on its packaging or in a document accompanying the device, the activity carried out together with its name, registered trade name or registered trade mark, registered place of business and the address at which it can be contacted, so that its location can be established.

For guidance, see **MDCG 2021-26**, which provides examples of repackaging and relabelling activities.

Should Article 16(4) certificates be recognized and uploaded to EUDAMED?

No, EUDAMED is the EU database for medical devices and in vitro diagnostic devices, which includes information about EU-certificates issued under the MDR and IVDR. EU certificates are linked to CE marking of devices. Article 16(4) Certificate is not an EU-Certificate and will not be uploaded to EUDAMED.

The required QMS for article 16(4) Certification needs to comply with ISO 13485, or can it comply with other QMS standards, such as ISO 9001 or 21 CFR Part 820?

The QMS for Article 16(4) Certification needs to comply with the requirements as listed in the MDR/IVDR Article 16(3).

The Article 16(4) Scheme is linked to the Notified Body and not to a Conformity Assessment Body accredited for ISO 13485 or ISO 9001. In the Article 16(4) Certification Scheme, the designated Notified Body will assess whether the QMS of the I/D complies with the QMS requirements as listed in Article 16(3) MDR/IVDR which is further specified in MDCG 2021-23.

The requirements listed in MDCG2021-23 are similar to a subgroup of requirements listed in ISO 13485. An audit can therefore be combined. However, Article 16(4) Certificate is issued by an EU MDR/IVDR designated Notified Body under the NB number while a QMS audit conducted against ISO 13485 is certified by a Conformity Assessment Body accredited by an accreditation organisation such as RVA, UKAS. 21CFR820 is USA legislation and does not apply in EU.

Does changing the intended purpose require a technical expert review?

Article 16(4) certification is limited to Article 16(2, 3, 4) where minor changes are made to devices which have no impact on the compliance of the device with the applicable requirements.

Changes in the intended purpose is addressed in MDR/IVDR Article 16(1)(b). In this case, the I/D becomes similar to a Legal Manufacturer who shall meet all the obligations of a Legal Manufacturer as described in Article 10. In case of changing the intended purpose of a device, the I/D shall assume the obligation of a Legal Manufacturer and should apply for the CE Certification Scheme which includes a full Conformity Assessment Process. All elements of Article 10 should be met when changing the intended purpose (including Article 10 (4) Technical Documentation).

Can you provide examples of Article 16(1) activities?

See Article 16(1) MDR/IVDR:

- Making the device available under the name and address of the I/D.
- Repackaging or relabelling that alters the device's intended use or claims.
- Modifying the device in a way that changes its original specifications or functionality.
- Changing components or features that affect the device's performance or safety.
- Adjusting packaging that could impact the device's integrity or usability.

In these cases, I/Ds are considered as they "are placing the device on the market" with new characteristics and they shall assume all manufacturer's obligations as described in Article 10 MDR/IVDR.

Can you provide examples of Article 16(2) activities? Some of these seem to be operations that would normally just be subcontracted by manufacturers and in accordance with technical documentation.

True. I/D modifying devices as defined in Article 16(2) (i.e., relabelling/repackaging) can conduct these changes under a subcontractor agreement with the manufacturer. The manufacturer has control over the final products. In case the I/D is conducting activities outside the control of the manufacturer, they need the Article 16(4) certificate.

Examples of Article 16(2) activities are provided in **MDCG 2021-26**. Article 16(2) applies when an I/D changes a device in a way that does not impact the compliance of the device with the applicable requirements.

In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

BSI and Article 16(4) Certification

Does BSI currently have any clients looking to take up this certification? What number of clients utilising this certification are envisaged in the coming months/years?

BSI is designated to issue Article 16(4) Certification since September 2024. We currently have ongoing applications under Article 16(4) Certification Scheme, but we are not able to anticipate how many Article 16(4) applications we can expect in the coming time. Note, transition times for MDR and IVDR has changed per (EU)2023/607 and (EU) 2024/1860) and legacy devices do not require an Article 16(4) Certification. For more information on Article 16(4) certification process with BSI, access our e-news **here**.

How many Article 16(4) certificates does BSI expect to issue?

We are not able to anticipate how many Article 16(4) applications we can expect in the future. However, the following shall be considered:

- National Competent Authorities of the EU Member States and EEA countries may start asking for Article 16(4) certificates more often in the near future.
- Transition times for MDR/IVDR moved to 2026/2027/2028 (MDR) and 2027/2028/2029 (IVDR).
- Legacy devices certified under the Directives do not require Article 16(4) Certification when relabelled and/or repackaged.
- Article 16(4) Certification is required for all Class devices without exemptions (MDR Class I, IIa, IIb, III and IVDR Class A, B, C, D).

Is BSI able to issue Article 16(4) certificates regardless of whether the Legal Manufacturer of the device is certified by BSI?

Regarding the relabelled/repackaged device, I/D can apply for the Article 16(4) Certification Scheme irrespective the Legal Manufacturer to hold an MDR/IVDR EU-Certificate with the same Notified Body or other Notified Body.

Any I/D can apply for Article 16(4) Scheme with a Notified Body (e.g., BSI). The Notified Body can accept the Article 16(4) application when:

- It is MDR/IVDR designated for the type of devices that are subject to activities mentioned in Article 16(2).
- It has an established Article 16(4) Certification Scheme that complies with the regulatory requirements as listed in Annex VII of MDR/IVDR.
- Meets the requirements listed in MDCG 2021-23.

Following an application, the Notified Body will carry out the process as set out in Annex VII of the regulations (i.e., pre-application, application review & contract, allocation of resources, conduct of conformity assessment activities – (in this case only a QMS Audit), reporting, final

review and decision and certification). Following a successful completion of the Conformity Assessment process, the Notified Body will issue an MDR and/or IVDR Article 16(4) Certificate attesting that the QMS of the I/D complies with the requirements laid down in Article 16(3).

Article 16(4) Certification can be granted to an I/D that relabelled and/or repackaged a device already placed on the Union market. Hence, the devices are CE-marked. Modified MDR/IVDR devices require an Article 16(4) Certificate. Legacy devices do not require an Article 16(4) certificate when relabelled/repackaged. Upon request, legacy devices may be added to the scope of Article 16(4) Certification (see **MDCG 2021-26**).

Note, Article 16(4) Certificates are issued to an Importer or a distributor. Article 16(4) Certificate is not issued to a manufacturer. However, in case a manufacturer acts as an I/D for devices from another manufacturer, they are eligible to apply for Article 16(4) certification as an I/D. Article 16(4) Certification is independent from any other certification. A client can apply for the Article 16(4) Certification as a stand-alone certification. In case a client applies for Article 16(4) Certification in combination with ISO 13485 Certification (i.e., multiple schemes), QMS audits can be combined.

Many sellers on online platforms offer devices that have been repackaged. When asked for copies of CE or ISO certifications, they are often unaware of what these are. How does BSI foresee ensuring that these sellers comply with the Article 16(4) requirements?

The supply chain is under control by the National Competent Authorities/Customs. Devices imported in an EU Member State are checked by Customs. In case of relabelled/repackaged MDR/IVDR certified devices, the National Competent Authorities will request Article 16(4) certificate from I/D who modified devices making them available in an EU Member state. Note, besides the obligations described in Article 16, I/D have obligations as described in Article 13 and 14 of the MDR/IVDR. The European Blue Guide also provides further information.

What are the audit content expectations for clients holding only an Article 16(4) certificate?

The requirements are outlined in Articles 16(2), 16(3) and 16(4). These requirements are further specified in **MDCG 2021-23.** QMS Audit will focus on these requirements.

Guidance on field examples

Can the manufacturer handle the distributor performing Article 16 (2) activities as a critical subcontractor instead of the distributor to get certified under Article 16(4)?

Yes. If the I/D carries out Article 16(2) activities under the control of the Legal Manufacturer, the I/D does not need an Article 16(4) certification.

The requirements in Article 16(4) state that I/Ds must have procedures in place to ensure they are informed of any corrective actions taken by the manufacturer to address safety issues or ensure compliance with Regulations. However, further clarification on the scope and boundaries of this obligation would be helpful. Is there any additional guidance or interpretation available on this?

Yes. See MDCG 2021-23 which provides further information on Article 16(4) Certification Scheme requirements. Furthermore, MDCG 2021-26 provides additional helpful information for I/D. The document provides extra guidance with respect to the requirements that should be met and will be audited by notified bodies. The guidance clearly states that I/D shall have an agreement with manufacturers where it is indicated that I/D are informed on nonconforming products and corrective actions from the manufacturer. Furthermore, the MDCG 2021-26 guidance provides information on the contents of Notifications Letters that should be sent to manufacturers and to Competent Authorities.

The Legal Manufacturer is typically familiar with its I/D and will add them to the supplier list. In the case of unknown parallel traders, the MDR/IVDR require them to inform the Legal Manufacturer of their activities in relation to Article 16(2). Please note, I/D shall also meet the obligations listed in Article 13 (importers) and Article 14 (distributors). One of the requirements is to check the devices from the Legal Manufacturer and inform the LM in case of nonconformities. Furthermore, they are required to cooperate to bring the nonconforming devices back into conformity. Parallel traders must also comply with Article 13 and Article 14 requirements related to nonconformities and corrective actions. On top of Article 13 and 14, I/D that relabel/repackage devices according to Article 16(2) shall meet the obligations described in Article 16(3, 4).

Could SaMD devices fall under Article 16(4)?

If the I/D's activities do not affect the performance or intended use of the device, while carrying out relabelling/repackaging activities according to Article 16(2), they shall assume the Article 16(3 and 4) obligations. For SaMD devices, the same principles apply. If a distributor repackages or relabels the software (e.g., by adding local language labels, changing the packaging), it would be subject to the requirements under Article 16(3, 4). Article 16 does not describe devices that are exempted from these requirements.

Is the approval from the original manufacturer required for relabelling and/or repackaging modifications?

No. I/Ds have to inform the Legal Manufacturer on their intention to conduct Article 16(2) activities on the devices placed on the EU/EEA market. Approval from the Legal manufacturer is not required. As indicated in the Law Suits (as referred to in the recital/whereas #38MDR and #36 IVDR), the LM has to accept the relabelling/repackaging by the I/D as long as the translation of information is accurate and up-to-date, that the activities mentioned in Article 16(2) are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. In case the LM is of the opinion that the requirements are not met, and the modified devices could have negative impact on its reputation, the LM could pursue Legal actions to stop the activities.

Regarding the need for an Extension to Scope (ETS) for new types of devices: for a QMS audit, this involves assessing processes, specifically those related to repackaging or relabelling activities. Should the scope be limited only to medical devices, or should it also include IVDs?

The MDR and the IVDR are separate regulations. As such, an I/D shall apply for the MDR Article

16(4) Certification Scheme when the subject devices are Medical Devices under the MDA/MDN codes (for codes see, Implementing Regulations 2017/2185) or apply for the IVDR Article 16(4) Certification Scheme when the subject devices are IVD devices under the IVR codes. In case an I/D relabels/repackages both MD as well as IVD devices, they should apply for both the MDR Article 16(4) Certification Scheme as well as the IVDR Article 16(4) Certification Scheme. Application for both schemes result in two (2) separate Article 16(4) Certificates. The MD Article 16(4) Certificate will only list the Types of Devices with the MDA and/or MDN codes while the IVDR Art 16(4) Certificate will list the Types of Devices with the IVR Codes. The QMS audit for the MD and IVD devices will be combined in one QMS audit.

As indicated in MDCG 2021-23 an ETS results in a notification leading to an on-site audit. Extension to scope may include:

- A new type of device added to the portfolio.
- A new Article 16(2) activity added to a type of device. In case a device is modified (e.g., relabelled and the I/D decides it should also be repackaged), that is considered a change in activity.
- If an I/D adds a new site where the Article 16(2) activities are conducted.

The Article 16(4) Certificate includes a scope listed (within BSI called a Devices Schedule) listing the types of devices subject to relabelling and/or repackaging. The Certificates will reference the EMDN codes of the devices. Furthermore, the Certificate defines the types of devices by their MDA or MDN code for the MDR Article 16(4) Certificate and the IVR codes for the IVDR Article 16(4) Certificate. Furthermore, the activities conducted on each type of device is listed. In case of broadening the scope by adding a new type of device not previously indicated on the certificate or adding a new activity on a particular type of device, the certificate needs to be supplemented. Because sites where the activities are conducted are not listed on the certificate and Extension to scope with respect to new sites will not impact the certificate.

If a manufacturer provides a distributor with Instructions for Use (IFUs), accessories and a CE-marked device, and then requests that the distributor creates a kit (with a shipper box also provided by the legal manufacturer) for a specific order, how should the distributor be classified in this situation?

Additionally, should the accessories be mentioned in the Declaration of Conformity (DoC)?

All the above will be carried out according to the manufacturer's instructions and the mutually signed agreement. In fact, the distributor's activities are subcontracted under the control of the manufacturer. The distributor does not require an Article 16(4) certificate when conducting activities under the manufacturer's QMS/control for devices that have not yet been placed on the market. Article 16(4) Certification applies to devices already placed on the Union Market.

The manufacturer will issue the final Declaration of Conformity. What needs to go into the DoC is described in Annex IV of the MDR/IVDR. Per Article 13 (General obligations of importers) and Article 14 (General obligations of distributors), I/D shall verify the contents of the DoC.

In case of procedure packs, see MDR Article 22.

If most of devices are relabelled/ repackaged to add local language labels, does this require submitting a notification for each shipment?

As indicated in MDCG 2021-26, one time notification is required (first shipment) unless additional changes (see MDCG) requiring new notifications are made.

If the Legal Manufacturer produces the device with the importer's requested label, does the importer still need to apply to the Notified Body for Article 16(4) Certification?

Article 16(4) Certification will be required for I/D who conduct relabelling/repackaging activities on CE-marked MDR/IVDR certified devices, after they have been placed on the EU/EEA market (i.e., post manufacturer's quality controls and final release). If the devices are relabelled under the control of the Legal Manufacturer, the I/D can be considered a subcontractor and does not require Article 16(4) Certification. In case the I/D conducts the activities outside the QMS control of the Legal Manufacturer, they will require Article 16(4) Certification. For example, a distribution centre of a large international company may not be covered by the Legal Manufacturer's QMS and work under its own QMS (e.g., ISO 13485-certified). In this case, the Distribution Centre needs an Article 16(4) Certification for their relabelling/ repackaging activities.

If a distributor cleans and repackages a non-sterile device (using packaging identical to that provided by the manufacturer) and the device still meets the manufacturer's specifications, does the distributor have any obligations under Article 16(4)?

It depends on what is meant by "cleaning". The cleaning step may have impact on the original condition of the device. In that case Article 16(1)(C) applies. Article 16(4) Certification is limited to changes to the outer packaging (including change of pack size) where the original condition of the device is not impacted.

A company imports Class I medical devices from outside the EU and acts as the exclusive distributor in the Member State where it is based. The importer agreement with the manufacturer, states that the importer replaces the original IFU sheet with its own translated version (approved by the manufacturer). Is an Article 16(4) Certificate required for this activity, or is there is an exemption if the importer is placing the product on the EU market for the first time?

In case the distributor holds a subcontractor-agreement with the manufacturer and the activities are under control by the manufacturer (IFU is approved by the manufacturer), the distributor does not need an Article 16(4) Certificate. In case the I/D conduct activities on devices already placed on the Union Market and the activities are outside the control of the Legal Manufacturer, they need an Article 16(4) Certificate.

Why choose BSI?

- World-leading experience and expertise.
- Accepting Article 16(4) applications since September 2024.
- Several ongoing Article 16(4) applications
- Visit our **Article 16(4) dedicated webpage**

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Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

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