# Article 16(4) Certification Scheme

## Importers & Distributors

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Regulatory Lead

2024 November

# **Article 16(4)** – Training Objectives

**Understand** the scope and requirements of Article 16 (sections 2, 3 and 4) of the MDR & IVDR

**Identify** the types of organisations eligible for Art16(4) Certification

**Understand** Conformity Assessment & Certification Process & Certification Cycle in BSI's Article 16(4) Certification Scheme

# Agenda

| A | General |
|---|---|
| 01 | Regulations: MDR & IVDR Article 16 |
| 02 | MDCG Guidance Documents Art 16(4) |
| 03 | Why, Who, What, When, How, Where |
| **B** | **BSI Article 16(4) Certification Scheme** |
| 04 | Conformity Assessment & Certification Process |
| 05 | Certification Cycle |
| 06 | Article 16(4) Certificate |
| | |

# Regulations: Article 16

(EU) 2017/745 (MDR) & (EU) 2017/746 (IVDR)

Do not confuse with **ANNEX XVI** – devices with non-medical purpose!

# **Art 16** – Cased in which mftrs obligations apply to importers, distributors

*Article 16*

**Cases in which obligations of manufacturers apply to importers, distributors or other persons**

1. A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

(a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;

(b) changes the intended purpose of a device already placed on the market or put into service;

(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

(a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device already placed on the market and of further information which is necessary in order to market the device in the relevant Member State;

(b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. 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.

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 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.

Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a 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. The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2 shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and, upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

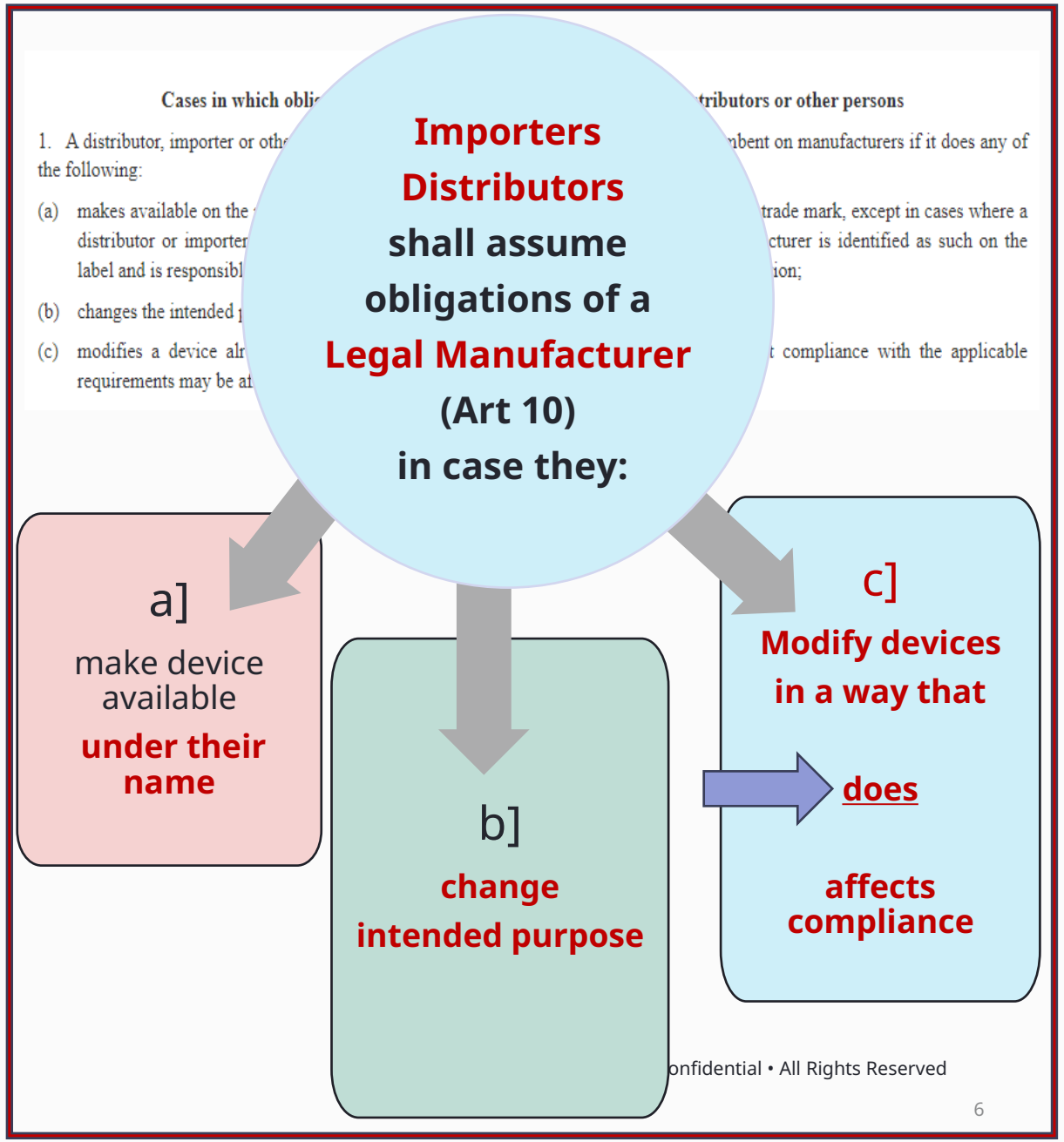
# **Art 16** – MDR / IVDR – Whereas (Preamble)

Recital: MDR (36) / IVDR (35)

To ensure legal certainty in respect of the obligations incumbent on economic operators, it is necessary to clarify when a distributor, importer or other person is to be considered the manufacturer of a device.

**Importer/Distributor (I/D) considered a manufacturer**

**➔ Art 16(1) ➔ CE-Marking Route**



# **Art 16** – MDR / IVDR – Whereas (Why)

Recital MDR (37) / IVDR (36) Parallel trade in products *already placed on the market* is a lawful form of trade within the internal market on the basis of: […]

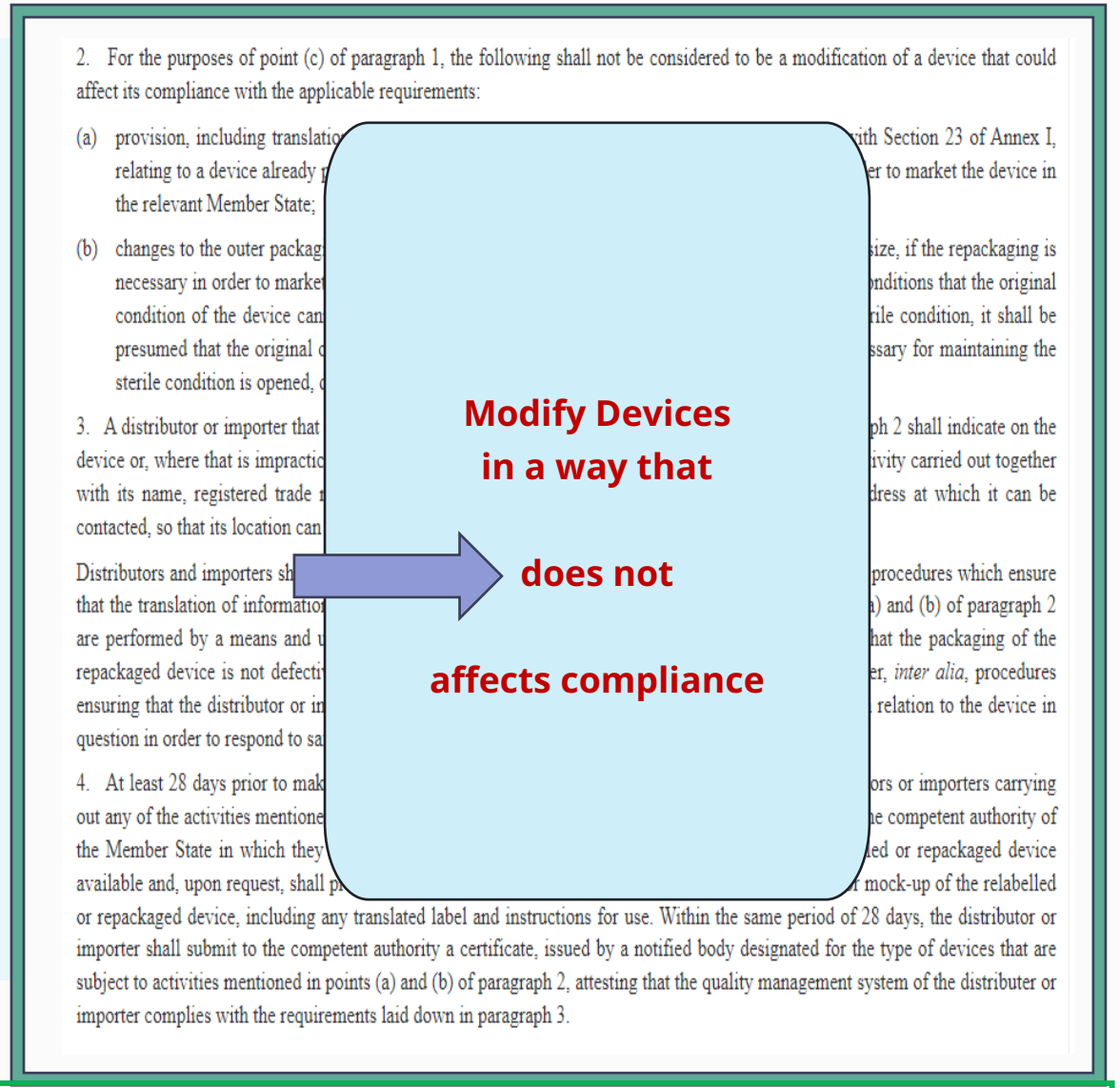
[…] requirements for relabelling and repackaging should be specified in this Regulation,

[…] taking into account the case-law of the EU Court of Justice […].

COURT OF JUSTICE OF THE EUROPEAN UNION

**Importer/Distributor (I/D) <u>not</u> considered a manufacturer**

**➔ Art 16(4) Certification Route**




**Obligations of a manufacturer do not apply ➔ Article 16(4) Certification route**

# MDR & IVDR - Article 16(2)

2. For the purposes of point (c) of paragraph 1, the following shall **not** be considered to be a modification of a device that could affect its compliance with the applicable requirements:

   a) provision, including translation, of the information supplied by the manufacturer, in accordance with Section 23 of Annex I, relating to a device **already placed** on the market and of further information which is **necessary** in order to market the device in the relevant Member State;

   b) changes to the outer packaging of a device **already placed** on the market, including a change of pack size, if the repackaging is **necessary** in order to market the device in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it.

      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.

# **MDR & IVDR Article 16(3) –** Requirements (I)

3. A distributor or importer that carries out any of the activities mentioned in points (a) and (b) of paragraph 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.

# **MDR & IVDR Article 16(3)** – QMS Requirements (II)

3. Distributors and importers shall ensure that they have in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by a 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.

The quality management system shall cover, *inter alia*, procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with this Regulation.

Conditions: meet legal requirements Art16(3) Quality Management System in place

# **MDR & IVDR Article 16(4) -** Communication

4. At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities mentioned in points (a) and (b) of paragraph 2

   shall inform the manufacturer and the competent authority of the Member State in which they plan to make the device available of the intention to make the relabelled or repackaged device available and,

   upon request, shall provide the manufacturer and the competent authority with a sample or mock-up of the relabelled or repackaged device, including any translated label and instructions for use.

# MDR & IVDR Article 16(4) - Certification

4. Within the same period of 28 days, the distributor or importer shall submit to the competent authority a certificate,

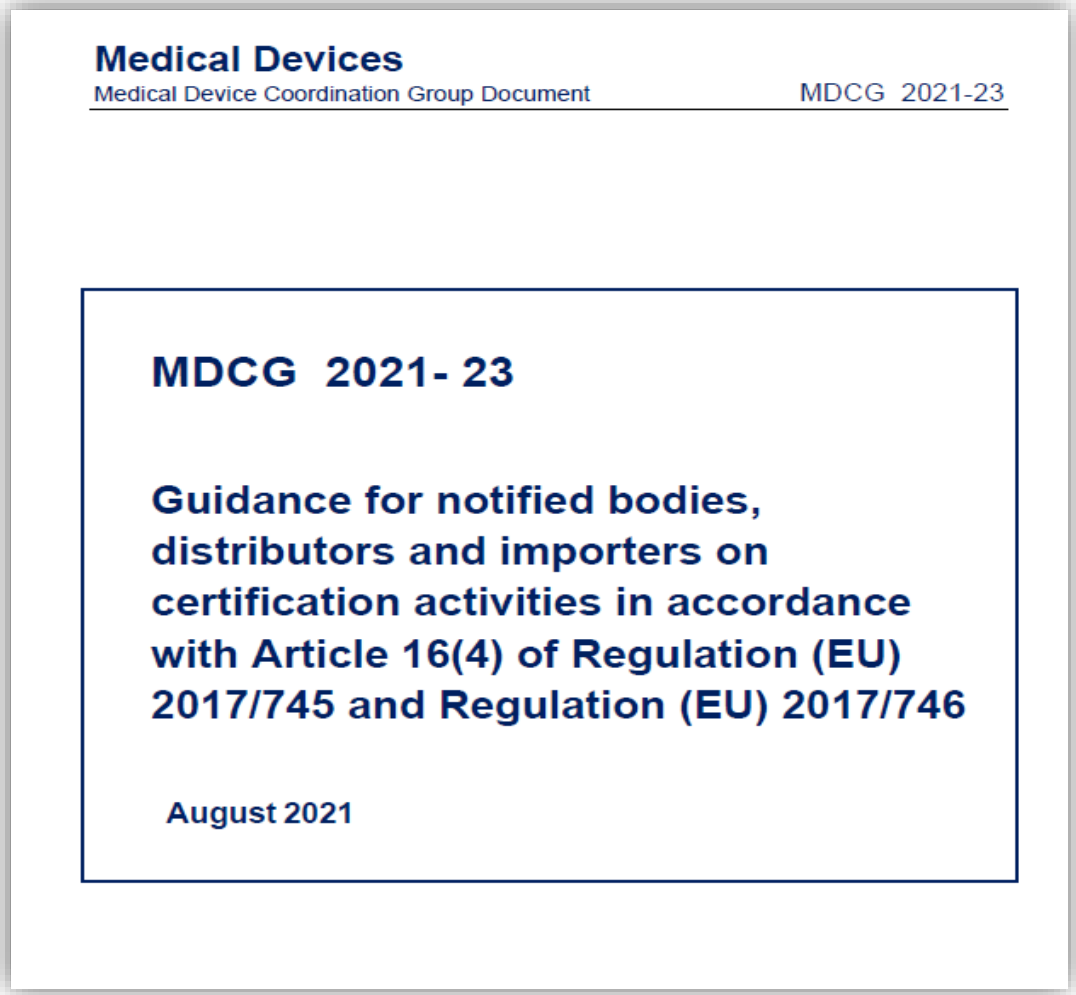
   issued by a notified body designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2,

   attesting that the quality management system of the distributer or importer complies with the requirements laid down in paragraph 3.

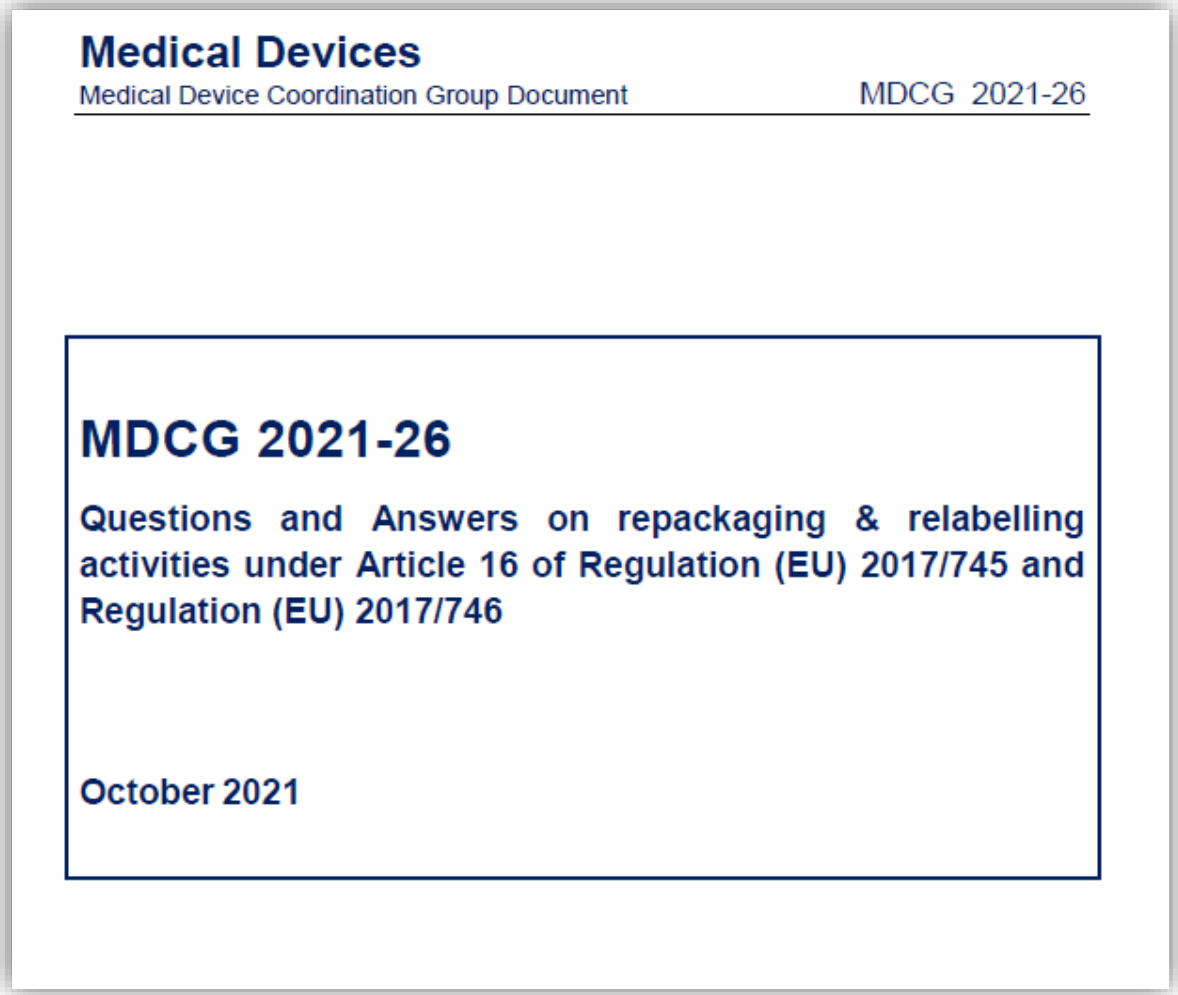
NB is designated for the **types of devices**, i.e., scope of designation indicated by MDN, MDA, IVR code as published on NANDO.

# MDCG Guidance Documents Art 16(4)

# **Article 16** – MDCG Guidance documents

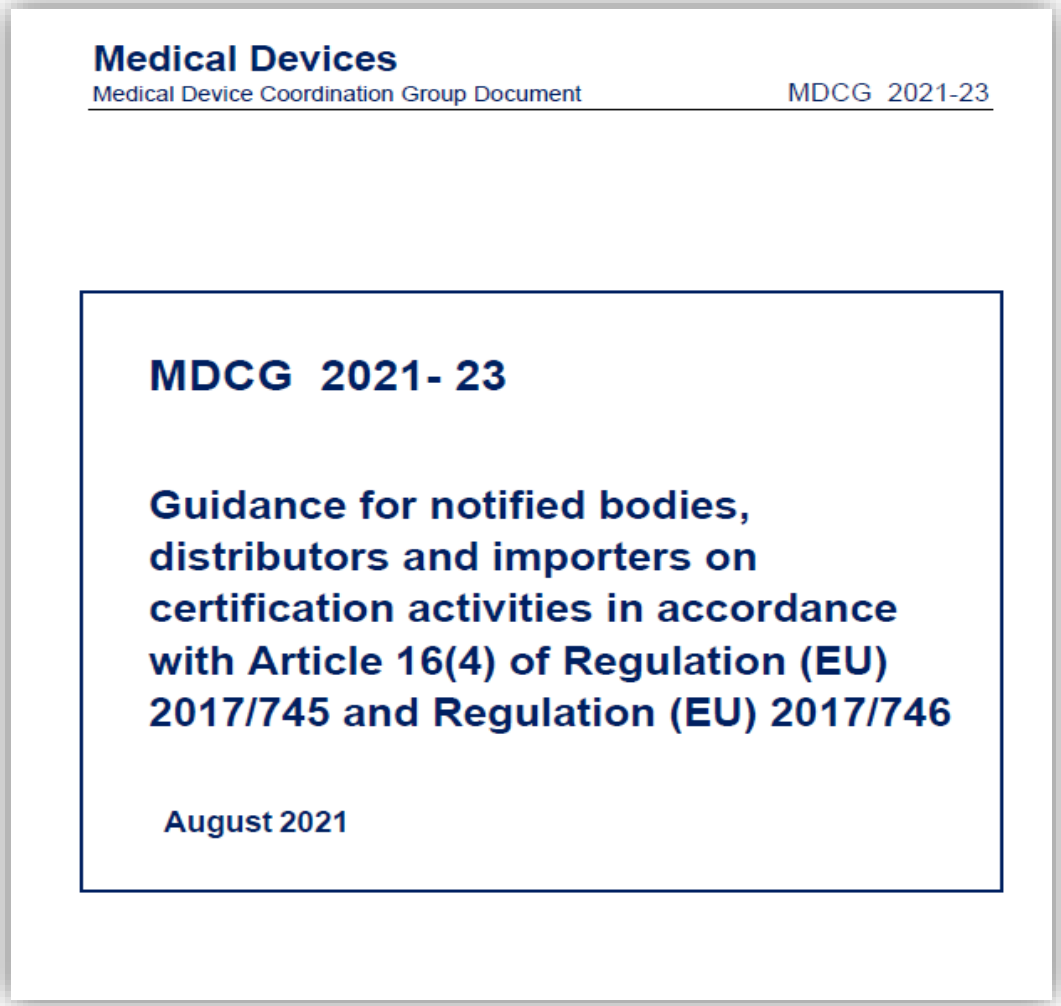



Guidance for Notified Bodies, importers & distributors




Guidance for Distributors & Importers

# **Article 16** – MDCG Guidance documents



**Medical Devices**
Medical Device Coordination Group Document MDCG 2021-23

**MDCG 2021- 23**

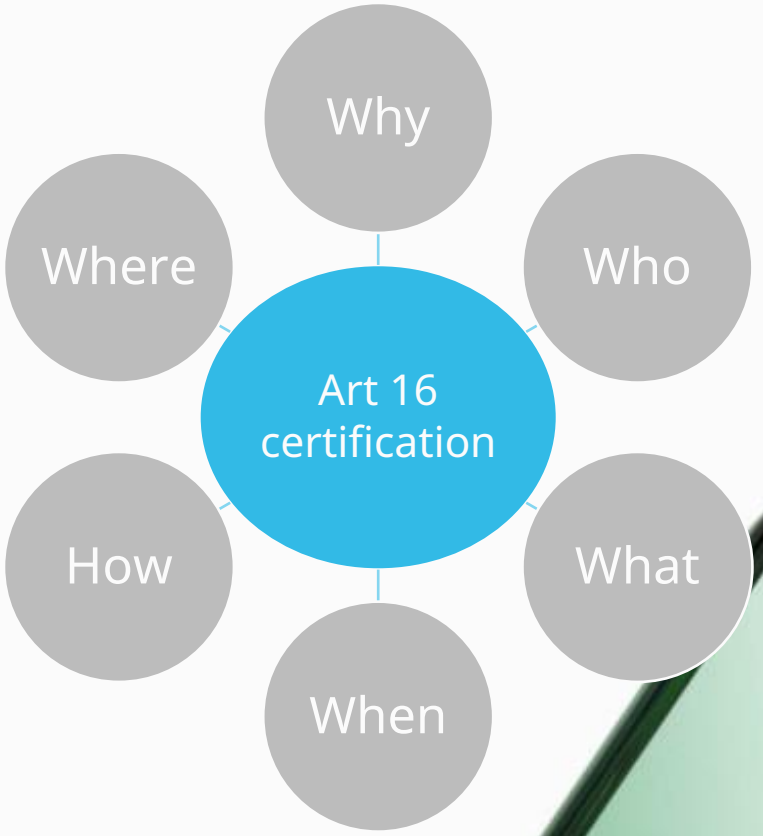
**Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746**

**August 2021**

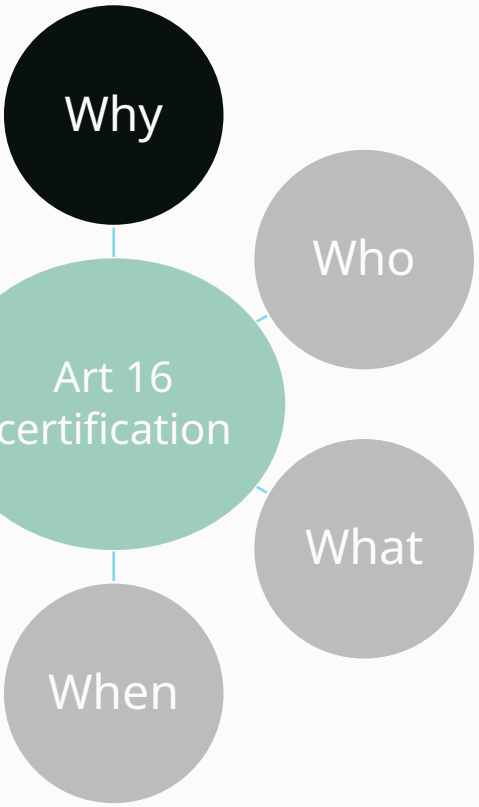
**CONTENTS**

- Introduction
- Scope: Guidance for NB to develop an Art 16(4) Cert Scheme establishing the assessment activities necessary to certify I&D's QMS.
- Quality Management System for distributors or importers
- Certification Scheme to be established by the Notified Body
- Contents of certificates
- Surveillance and changes, including extensions to scope
  - Auditing
  - Assessment of change notifications

# Why, Who, What, When, How, Where



# **Article 16(4) certification** – Why (I)




**Why is Art 16(4) certification required?**

It is a legislative requirement for importers / distributors who are undertaking relabelling or repackaging of devices already placed on the market. Hence, Art 16(4) Certification Scheme is a Regulatory Scheme linked to a MDR / IVDR designated NB.

Art 16(4) Scheme is not an "Accredited Scheme" like ISO

Art 16(4) certificate is not an EU (CE) Certificate (Annex XII)

**Why Art 16(4) Certificate needed?**

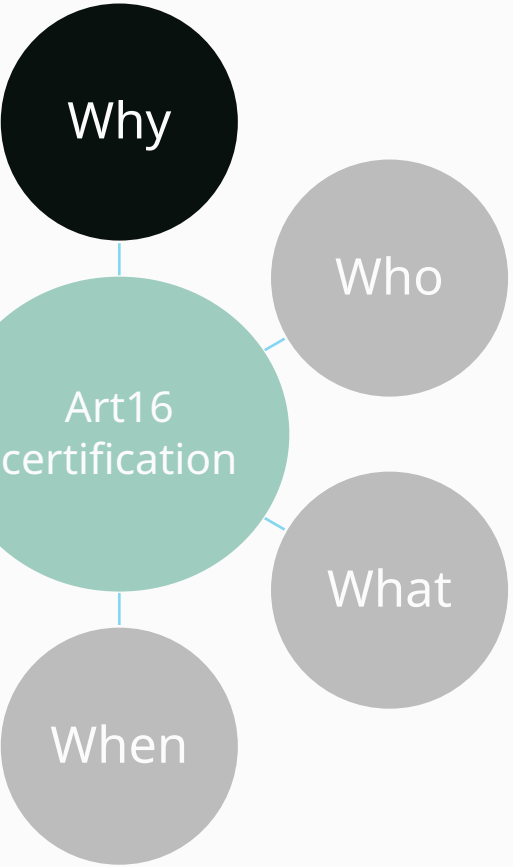
To submit certificate to CA of MS prior to market the relabelled / repackaged device in that MS

**Why is Art 16 introduced?**

To improve **transparency** (key pillar of MDR/IVDR). It makes clear who is the actual legal mftr and who is the 3rd party I/D (parallel distributors) conducting relabelling / repackaging of devices already placed on the market.

Art 16(4) certification will ensure free trade in local EU markets and expand the control by the CAs. Art 16 will ensure regulatory compliance of the I/D.

# **Article 16(4) certification** – Why (II)




**Why are relabelling / repackaging activities conducted?**

- Modifications are **"Necessary in order to market"** refers to conditions that should be met in order to market the device in a specific Member State.

**What is necessary?**

- I/D to provide a rationale why a change is "necessary".
- NB to analyse the reasoning of the change.
- Mftr to analyse the (reason of) the change & implement follow up actions
- CA to analyse "the compliance with national requirements"

# **Article 16(4) certification** – Who (I)

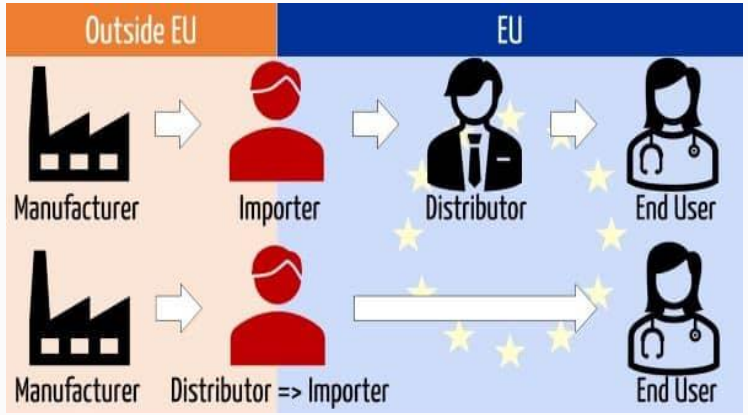
Who

What

**Who need certification under Article 16(4) ?**

I/D based in **"European Economic Area (EEA)** who carry out relabelling / repackaging of MD that is already placed on the **EEA** market:

- EU Member State,
- EFTA Countries (Norway, Iceland, Liechtenstein),
- Northern Ireland (Brexit agreement / EU Blue Guide)




# **Article 16(4) certification** – Who (I)

Who

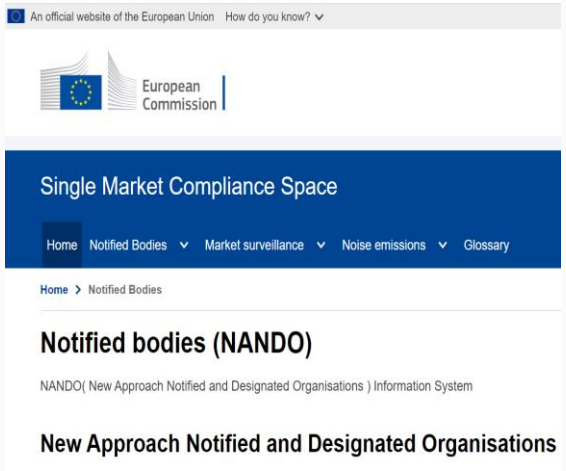
What

**Who issues Art 16(4) certificates?**

Notified Bodies designated for MDR/IVDR

Scope of designation (indicated by MDA, MDN, IVR codes on NANDO) include types of devices being modified.

If yes, NB can undertake certification activities related Art 16 (2, 3, 4).


| | | |
|---|---|---|
| MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) |
| MDN 1204 Non-active non-implantable devices for wound and skin care | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) |
| MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) |
| | Conformity | |

# **Article 16(4) certification** – What (scope) (I)

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What

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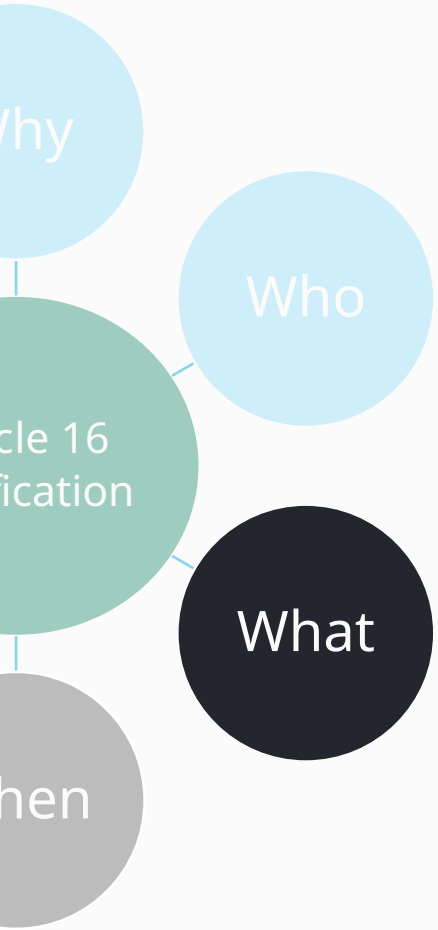
**What activities certified under Article 16(4)?**

Relabelling (Rel) Art 16(2a) = provision, incl. translation, of the information, including the Instructions for Use, supplied by the manufacturer in accordance with section 23 of Annex I, relating a device already placed on the market and of further information which is necessary in order to market the device in the relevant MS.

Repackaging (Rep) Art 16(2b) = changes to the outer packaging of a device already placed on the market, if the repackaging is necessary to market the device in the relevant MS and if it is carried out in such conditions that the original condition of the device cannot be affected by it.


# **Article 16(4) certification** – What (scope) (II)




**What Type of Devices will be certified under Article 16(4)?**

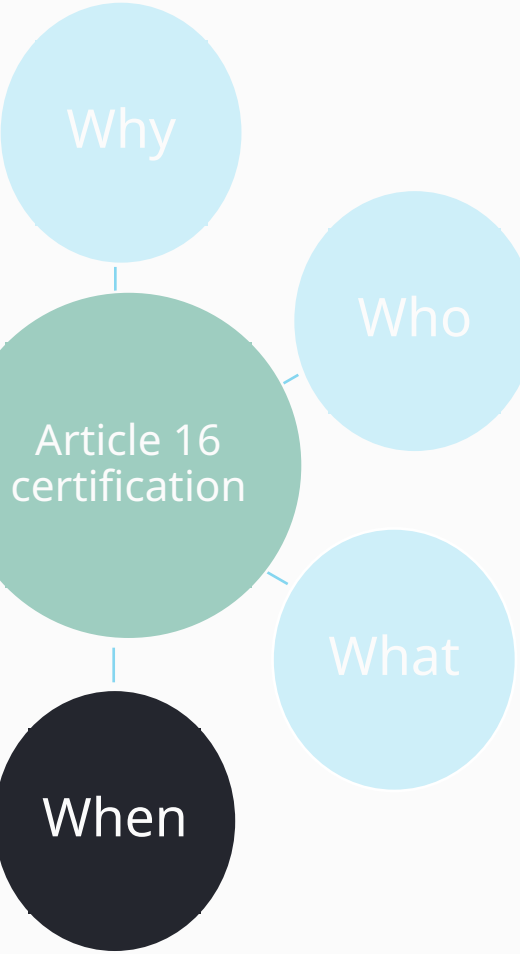
Types of Devices under MDR and IVDR Certification as defined by the codes published in the Implementing Regulation 2017/2185.

Irrespective of classification: All Class I, IIa, IIb, III, A, B, C, D devices are in-scope. There are no exemptions.

**What is out of scope?**

- For devices in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the packaging that is necessary to **maintain the sterile condition** is opened, damaged or otherwise negatively affected by the repackaging (Art 16(2b)
- **Legacy Devices** under EC Certification are out of scope, i.e., do not require Art 16(4) cert. if relabelled / repackaged.
- **Health institution/hospital** splitting up a large pack of devices into smaller pack sizes or individual units for use or circulation **within** the health institution/hospital does **not** need Art 16(4) cert.

# **Article 16(4) certification** - When




- At least 28 days prior to making the relabelled or repackaged MD available on the market, I&D carrying out the Art 16(2) activities shall inform the Mftr and the CA of the MS in which they plan to make the MD available of the intention to make the relabelled or repackaged MD available.
- Within the 28 days-period prior to making the relabelled and/or repackaged MD available on the market, I&D shall submit Art 16(4) certificate to the CA of the MS.

What should be included in the Notification? ➔ MDCG 2021-26

What is the impact of the Notification?
- Impact on Manufacturers:
- Impact on CA of MS:

# Article 16(4) – Impact on Manufacturers

Manufacturers:

- Consider the relabelling / repackaging activities of I/D.
- Study the necessity and the quality of the activities,
- Protect against inadequate translations & inappropriate repackaging

- Controls in place to:
  - Evaluate the information provided and the modifications implemented
  - Request sample /MU / Labelling
  - Include the modified products in the PMS plan (Post Market Surveillance / vigilance reporting),
  - Add the parallel distributor to distributors list and consider them in case of FSCAs / withdrawals / recalls and request cooperation.

# Article 16(4) – Impact on Competent Authority

Competent Authority:

Based on the Notification & provided sample/mock-up/labelling & Art16 Certificate …

- CA can expand the control of the Importers & Distributors (e.g. during an inspection) and better conduct market surveillance of the relabelled / repackaged products.

- CA is aware the I/D
  - has a QMS which has been audited and certified by a NB
  - is under surveillance control by the NB.
  - CA can contact the NB that issued the Art16(4) Certificate, if necessary.

# **Article 16(4) certification** – How (I)

**How to obtain an Article 16(4) certificate from NB?**

1] Select appropriate NB(s):

- Designated for MD & IVD types of devices subject to modification (in scope)
- Check the NB's scope of the designations in NANDO

2] Apply with NB(s):

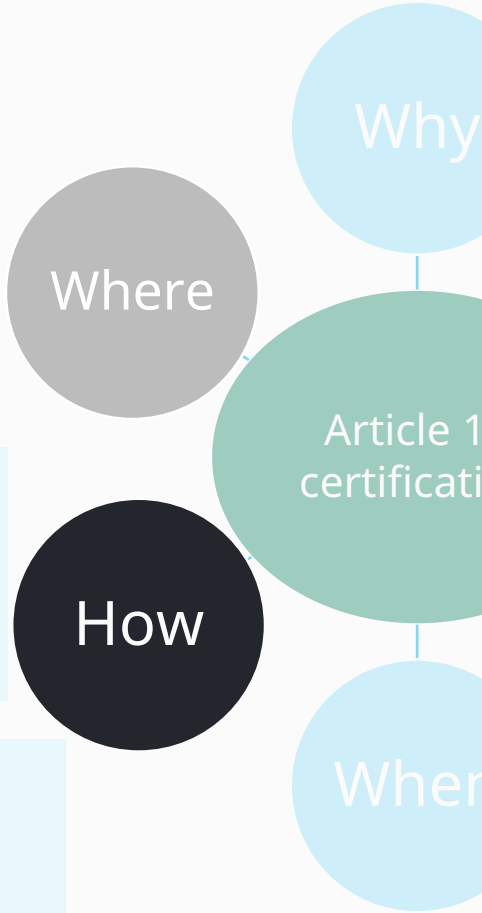
- When changing MDR and IVDR devices => two separate applications MDR + IVDR.
- Result in MDR Art 16(4) Cert + IVDR Art 16(4) Cert.

3] Follow NB's Conformity Assessment & Certification process:

- Conformity Assessment & Certification process MDR/IVDR Annex VII.
- NB will conduct QMS audit against Art 16(3) requirements (MDCG 2021-23).
  - Art 16(4) Scheme does not include Technical Documentation Review or Microbiology audit

4] Certification Cycle & Post Certification Activities: Initial, surveillance, recertification audit,

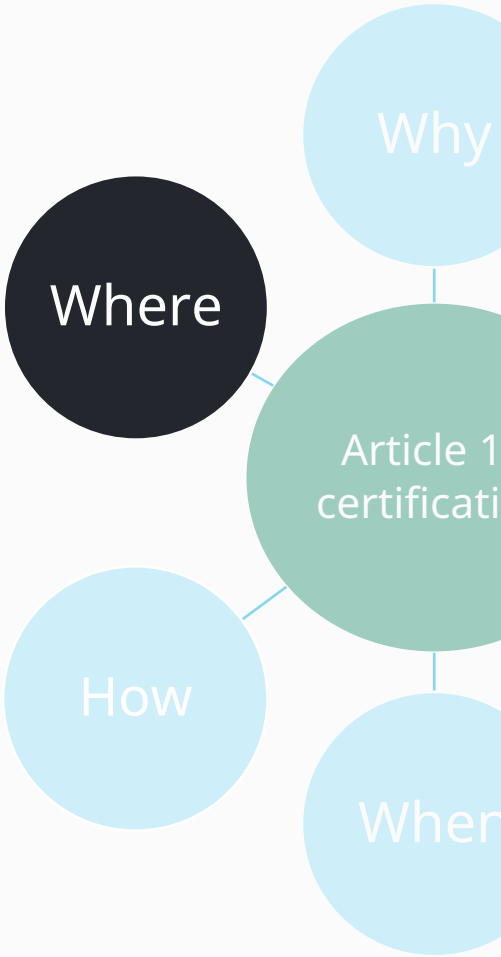
5] Additional Audits related to proposed (major) changes (e.g. Extension to Scope)




# **Article 16(4) certification** - Where

**Where will the Notified Body audit?**

- Importer/Distributor sites where Art 16(2) activities are conducted
- The sub-contractor sites involved in relabelling / repackaging activities



# BSI’s Article 16(4) Certification Scheme

# Article 16(4) – Conformity Assessment & Certification Process

Conformity Assessment Process steps per Annex VII (4) of MDR / IVDR similar to CE Scheme

| Enquiry | Pre-application Activities & Quotation | Application review & Contract & Allocation of resources | **QMS audit** Planning on-site audit Reporting | Final review & Decision making | Certification | Changes & Modifications Surveillance Audit Post-certification monitoring Recertification | Certificate Withdrawal |
|---|---|---|---|---|---|---|---|
| Commercial | Commercial | Scheme Manager |   | Scheme Manager Certificate Decision Maker | | QMS Auditor Scheme Manager Certificate Decision Maker | |

QMS Audit Only. => No Technical Documentation Review & No Microbiology Audit

# **Article 16(4)** - Certification Cycle (BSI approach)


**Certification Scheme: = 3 Years Certification Cycle ➔ Certificate Validity 3 Years**

- Initial Certification: QMS audit on-site: All Art 16(2) activities / All types of devices / All sites.
- Surveillance audit: **1x** Mid-term [stand-alone Art 16(4)]: on-site

-– or –

- Surveillance audit: **2x** Annual [=audit combined with ISO13485/other scheme audit]: on-site
- Re-certification audit for Certificate Renewal: on-site.
- Surveillance audits after Certificate Renewal: on-site
- Additional Audits (e.g. Notifications of major changes; Extension to Scope: Audit on-site)

# Application for Article 16(4) Certification

# **Article 16(4)** –Application Portal

Select Services | Company Information | Add Devices | Add Sites | **Supporting Documents** | Other Information | Declaration | Submit

## Medical Device Related Services

1 **Service**

Service

--- Select a value ---

Search

ISO 9001:2015 (UKAS)
ISO 9001:2015 (ANAB)
Training
Safety Testing (IEC 60601 and/or EMC)
Japan PMD Act certification
Malaysia CAB product approval
Accelerated Medical Device Registration in Taiwan (Applicable only to EU Manufacturers)
Malaysia - Good Distribution Practice for Medical Devices (GDPMD) (Applicable only to Malaysia manufact...
Singapore - Good Distribution Practice for Medical Devices Singapore (GDPMDS) (Applicable only to Sing...
Article 16(4) for MDR
Article 16(4) for IVDR

Complete all fields to add a service

## Medical Device Related Services

Service

Service

Article 16(4) for MDR

Are all of your sites relating to your Article 16(4) application based in the EU/EEA or Northern Ireland? *

Yes | No

Article 16(4) is not applicable for site(s) not based in the EU/EEA or Northern Ireland. Please select Exit and select an alternative service

EXIT | SUBMIT

Complete all fields to add a service

## Device Information: Art 16(4) MDR

1 **Device Details**

2 Activity Type

**Device Details**

Code guidance can be found at https://webgate.ec.europa.eu/dyna2/emdn/

**Device Nomenclature Code** *

M040303 7/255

Where possible, please provide 1 letter and at least 6 digits.

**Product Name** *

Test Device 11/255

List manufacturer product name (brand name).

Code guidance can be found at https://eur-lex.europa.eu/eli/reg_impl/2017/2185/oj

**MDR Code (Commission Implementing Reg (EU) 2017 / 2185)** *

MDN 1214 General non-active non-implantable devices used in health care and other non-active no...

Specify the MDR code that applies.

CANCEL

## Device Information: Art 16(4) MDR

Device Details

2 **Activity Type**

**Activity Type**

**Activity Type** *

--- Select Activity Type ---

--- Select Activity Type ---
Relabelling
Repackaging
Relabelling & Repackaging

CANCEL | < BACK

## Site Details

**Location Type** *

Manufacturer Additional Site

Guidance on identifying a Critical Subcontractor/Crucial Supplier

**Site Name** *

Site 2 6/255

**Site Country** *

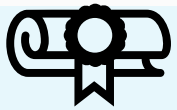
--- Select a country ---

Search

--- Select a country ---
Austria
Belgium
Bulgaria
Croatia
Cyprus
Czechia
Denmark
Estonia
Finland
France

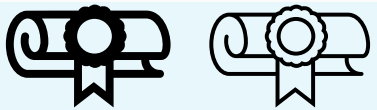
For each site, please select the service(s) which include that site within the scope.

# **Article 16(4)** – Quotation – Audit Cycle



Stand-alone Article 16(4)

- Initial Audit
- **Surveillance Audit after 18 months**
- Recertification Audit in **Year 3**



Article 16(4) + other scheme(s) e.g. ISO 13485 ISO 9001, MDSAP

- Initial Audit
- **Surveillance Audit in Year 1**
- **Surveillance Audit in Year 2**
- Recertification in **Year 3**

# Article 16(4) – Proposal

## Application information

### Contract for services for Feebris Ltd

This document has been produced based on the information provided during discussions and should accurately reflect your business need based on those facts.

This contract for services covers the following products / services:

**Article 16(4) MDR Initial Contract - AGA TEST2**

Before signing please review this document carefully. If for any reason you feel it needs amending, please contact us to discuss your revised requirements.

The BSI Parties:

**BSI Group The Netherlands B.V.,** a corporation with registration number 33264284, its principal address being at Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands. The competent authority for this company is the Ministry of Health, Welfare and Sport of the Dutch government.

Client details

| | |
|---|---|
| **Client name:** | Feebris Ltd |
| **Address:** | Accelerator London, 35 Kingsland Road<br>London<br>E2 8AA<br>GB |
| **Company registration number:** | |
| **VAT number:** | |
| **Contact name:** | Forrest Griffin |
| **Phone number:** | 07870763266 |
| **Email address:** | forrest@ufc.com |

Invoice details

| **Client name:** | |
|---|---|

**Article 16 MDR Scope Statement**

[CODE] - Contact lenses - repackaging

[CODE] - Wound dressings - relabelling

Site(s) selected for assessment

Days shown in the following table are only those 'formal' assessment days required before the certificate is issued by BSI and the sites they relate to. Stage 2 / Other includes any initial Extension to Scope or Transfer Assessment visits.

| Country | City | Address | Registration path |
|---|---|---|---|
| GB | London | Accelerator London<br>35 Kingsland Road | New Registration |

| Site Name | City | No of Employees | Site activities |
|---|---|---|---|
| Feebris Ltd | London | 18 | repacking & relabelling |

## Quotation

**Site Name: Feebris Ltd**

| Description | Q |
|---|---|
| Annual Management Fee - Article 16 | |
| Application Fee - Article 16 | |
| QMS Audits - Initial - Stage 1 - Assessment visit | |
| QMS Audits - Initial - Stage 1 - Offsite planning and reporting hours | |
| QMS Audits - Initial - Stage 2 - Assessment visit | |
| QMS Audits - Initial - Stage 2 - Offsite planning and reporting hours | |

Offsite planning and reporting time will be charged in half-day
Microbiology audits. For larger durations the corresponding pla

Estimated Maintenance Costs

**Site Name: Feebris Ltd**

| Description | Q |
|---|---|
| Article 16 Certificate Renewal | |
| QMS Audits - Year 1 - Assessment visit | |
| QMS Audits - Year 1 - Offsite Planning and Reporting | |
| QMS Audits - Year 2 - Assessment visit | |
| QMS Audits - Year 3 - Recertification visit | |
| QMS Audits - Year 3 - Offsite Planning and Reporting | |

## Proposal

### Contract for Services

Feebris Ltd - Healthcare - Article 16 MDR Initial Contract - TRAINING EXAMPLE

Prepared by: Agnieszka Latka

Reference number: Q820213

Date: 17 September 2024

bsi.

# Art 16(4) QMS Audit - elements

# **QMS of Importers / Distributors** – MDCG 2021-23 [Art 16(4) reqs specified] - I

**MDCG 2021-23**

## Contractual relationships

QMS procedures should address elements related to **contractual relationships**:

- Contracts I&D with any economic operator the I&D is purchasing the device from should ensure that I&D is informed in a timely manner about any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the Regulation
- Contract between I&D and NB should specify the possibility for NB to perform on-site audits at the premises of I&D or their subcontractors

**QMS** should govern the structure, responsibilities, procedures, processes and management of resources required to implement the principles and actions necessary to achieve compliance with the Art 16(3) provisions

**Goal:** Procedures should ensure that activities do not affect compliance of the device with the applicable requirements.

# **QMS of Importers / Distributors** – MDCG2021-23 [Art 16(4) reqs specified] - II

**MDCG 2021-23**

QMS should be capable of supporting / demonstrating consistent achievement of the Art 16(3) requirements and should cover and address at least the following:

- Documentation of the management system, incl. responsibility of the management and development of policies & procedures
- Resource management, incl. premises & equipment necessary to carry out activities as well as selection and control of suppliers and sub-contractors
- Policies for assignment of activities / responsibilities to personnel ensuring the availability of resources and information necessary to support the operation and monitoring of the activities mentioned
- Management of corrective actions:
  - procedures ensuring that I&D is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the regulation
  - procedures for handling non-conforming devices and market recalls due to Art 16(2) activities, incl., when necessary, field safety corrective actions and verification of their effectiveness,
- Procedures to ensure traceability of the devices as well as labels, instructions for use and outer packaging indicating the changes made to the product. Note, sub-lot number of the relabelled / repackaged devices or other information may be provided to ensures traceability of those devices (MDCG2021-26).
- Control of documents & records
- Supervision of the implementation and maintenance of QMS, incl. internal audits and MR

# **QMS of Importers / Distributors** – MDCG2021-23 vs. ISO13485

**MDCG 2021-23**

**QMS** should be capable of supporting / demonstrating consistent achievement of the Art 16(3) requirements and should cover and **address at least the following**:

ISO 13485 Clause 4 & 5

- the management system, incl. responsibility of the management and development of policies

ISO 13485 Clause 6

- Resource manag… premises & equipment necessary to carry out activities as well as selection and control of s… ractors

ISO 13485 Clause 8.3 & 8.5

- Policies for assignment of activities / responsibilities to personnel ensuring the availability of resources and information necessary to support the operation and monitoring of the activities mentioned
- Management of corrective act…
  - procedures ensuring that I&D is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it into conformity with the regulation
  - procedures for handling non-conforming devi… lls due to Art 16(2) activities, incl., when necessary, field safety corrective actions and … fectiveness,

ISO 13485 Clause 7.5.9

- Procedures to ensure traceability of the devices as well as labels, instructions for use and outer packaging indicating the changes made to the product. Note MDCG2021-26, sub-la… he relabelled / repackaged devices or other information may be provided to ensures traceabilit…

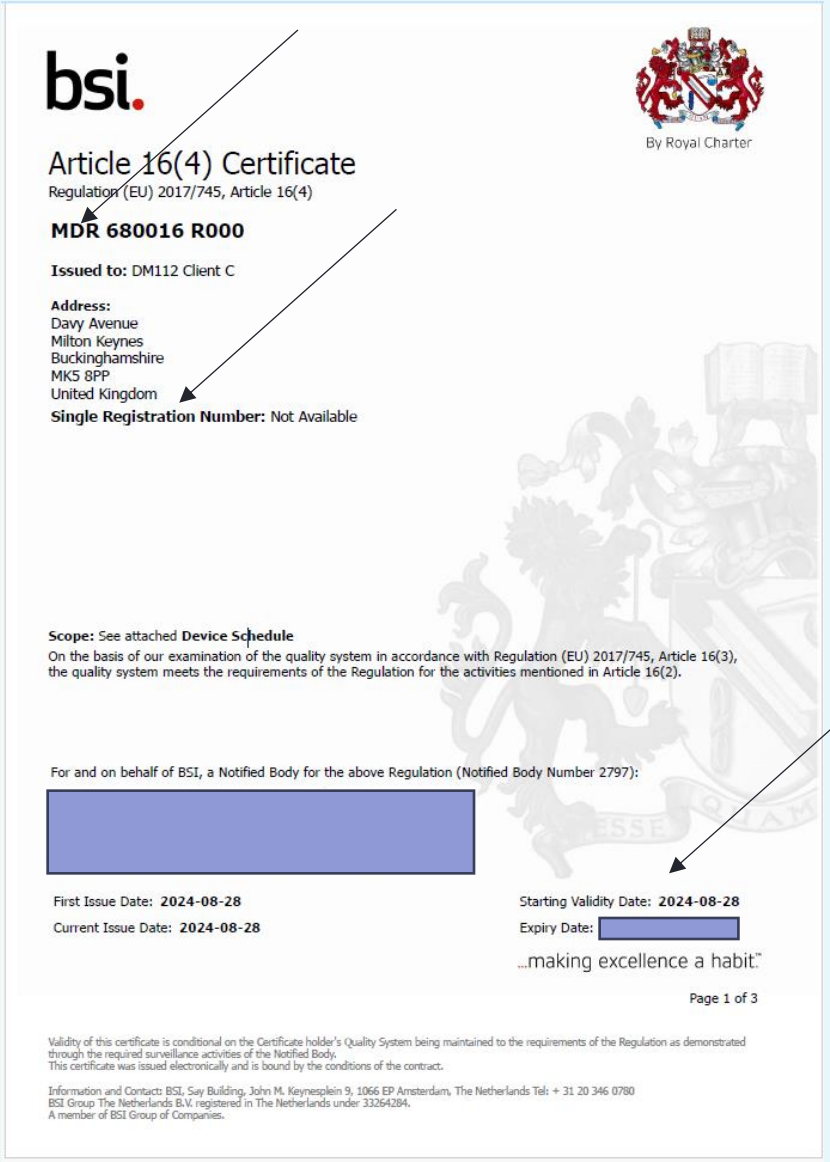
ISO 13485 Clause 4.2

- Control of documents & records
- Supervision of the implementation and maintenance of QMS, incl. internal audits and MR

ISO 13485 Clause 5.6/8.2

# Article 16(4) Certificate

# **Article 16(4)** – Certificate (example - MDR)



bsi.

By Royal Charter

## Article 16(4) Certificate

Regulation (EU) 2017/745, Article 16(4)

**MDR 680016 R000**

**Issued to:** DM112 Client C

**Address:**
Davy Avenue
Milton Keynes
Buckinghamshire
MK5 8PP
United Kingdom

**Single Registration Number:** Not Available

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Article 16(3), the quality system meets the requirements of the Regulation for the activities mentioned in Article 16(2).

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

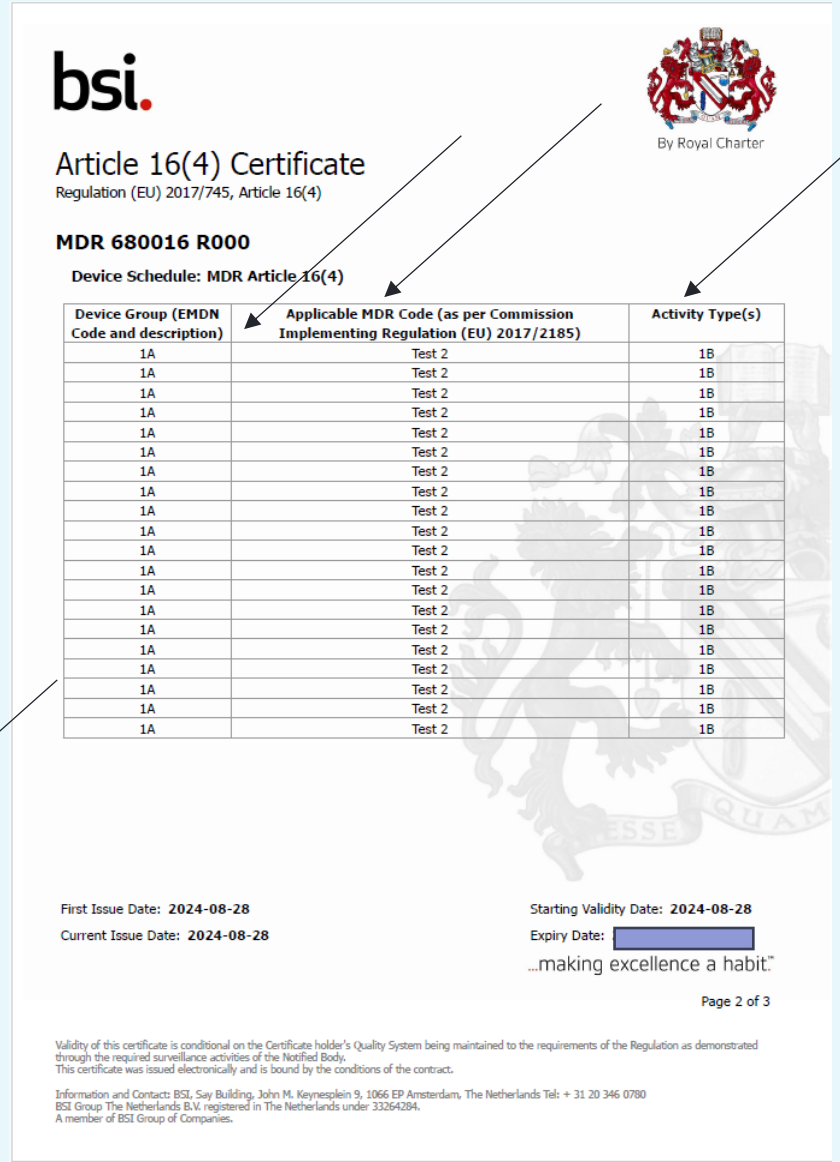
First Issue Date: **2024-08-28**
Current Issue Date: **2024-08-28**

Starting Validity Date: **2024-08-28**
Expiry Date: [redacted]

...making excellence a habit.™







bsi.

By Royal Charter

## Article 16(4) Certificate

Regulation (EU) 2017/745, Article 16(4)

**MDR 680016 R000**

**Device Schedule: MDR Article 16(4)**

| Device Group (EMDN Code and description) | Applicable MDR Code (as per Commission Implementing Regulation (EU) 2017/2185) | Activity Type(s) |
|---|---|---|
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |
| 1A | Test 2 | 1B |

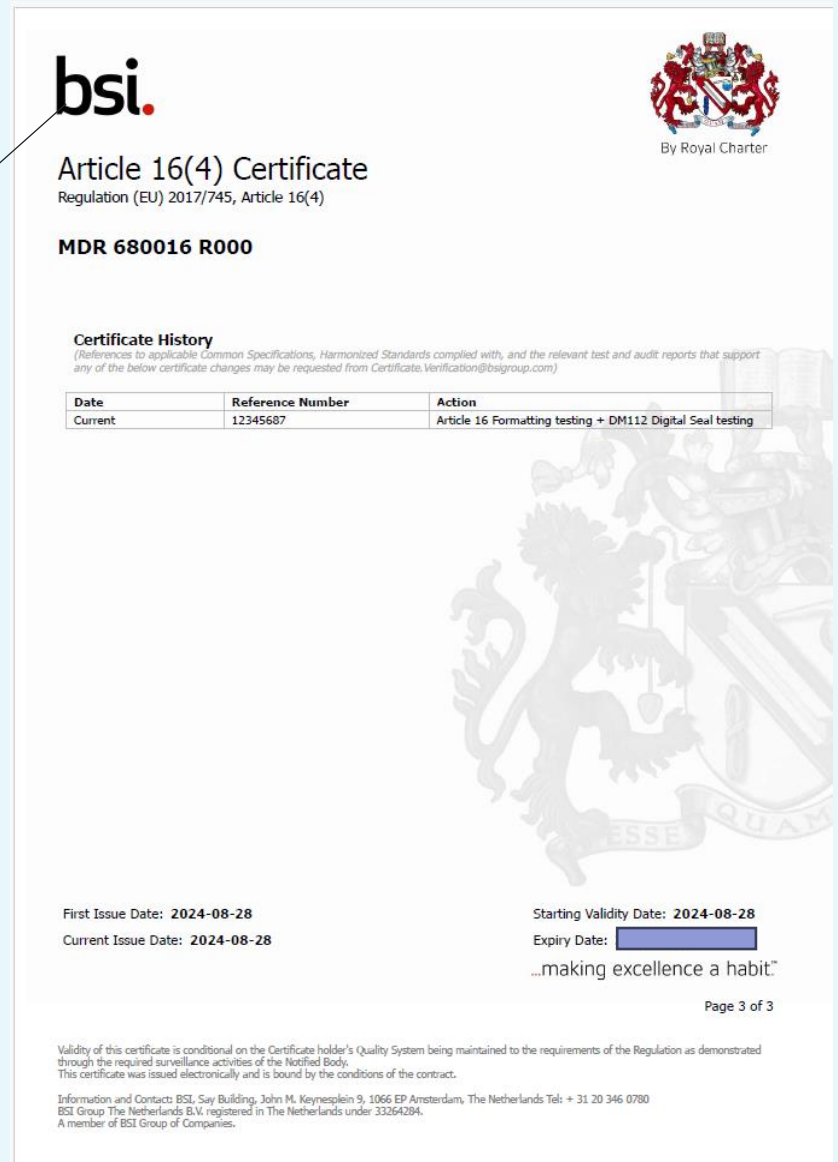
First Issue Date: **2024-08-28**
Current Issue Date: **2024-08-28**

Starting Validity Date: **2024-08-28**
Expiry Date: [redacted]

...making excellence a habit.™







bsi.

By Royal Charter

## Article 16(4) Certificate

Regulation (EU) 2017/745, Article 16(4)

**MDR 680016 R000**

**Certificate History**

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

| Date | Reference Number | Action |
|---|---|---|
| Current | 12345687 | Article 16 Formatting testing + DM112 Digital Seal testing |

First Issue Date: **2024-08-28**
Current Issue Date: **2024-08-28**

Starting Validity Date: **2024-08-28**
Expiry Date: [redacted]

...making excellence a habit.™

# **Article 16(4)** – Scope of Certificate: Types of Devices (EU) 2017/2185)

## ANNEX I

**The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745**

**I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**

**A. Active devices**

1. *Active implantable devices*

| MDA CODE | Active implantable devices |
|---|---|
| MDA 0101 | Active implantable devices for stimulation/inhibition/monitoring |
| MDA 0102 | Active implantable devices delivering drugs or other substances |
| MDA 0103 | Active implantable devices supporting or replacing organ functions |
| MDA 0104 | Active implantable devices utilising radiation and other active implantable devices |

2. *Active non-implantable devices for imaging, monitoring and/or diagnosis*

| MDA CODE | Active non-implantable devices for imaging, monitoring and/or diagnosis |
|---|---|
| MDA 0201 | Active non-implantable imaging devices utilising ionizing radiation |
| MDA 0202 | Active non-implantable imaging devices utilising non-ionizing radiation |
| MDA 0203 | Active non-implantable devices for monitoring of vital physiological parameters |
| MDA 0204 | Other active non-implantable devices for monitoring and/or diagnosis |

3. *Active non-implantable therapeutic devices and general active non-implantable devices*

| MDA CODE | Active non-implantable therapeutic devices and general active non-implantable devices |
|---|---|
| MDA 0301 | Active non-implantable devices utilising ionizing radiation |
| MDA 0302 | Active non-implantable devices utilisin |
| MDA 0303 | Active non-implantable devices utilisin |
| MDA 0304 | Active non-implantable devices for sho |
| MDA 0305 | Active non-implantable devices for stir |
| MDA 0306 | Active non-implantable devices for ext |
| MDA 0307 | Active non-implantable respiratory dev |
| MDA 0308 | Active non-implantable devices for wo |
| MDA 0309 | Active non-implantable ophthalmologi |
| MDA 0310 | Active non-implantable devices for ear |
| MDA 0311 | Active non-implantable dental devices |
| MDA 0312 | Other active non-implantable surgical d |
| MDA 0313 | Active non-implantable prostheses, dev |
| MDA 0314 | Active non-implantable devices for pro fertilisation (IVF) and assisted reprodu |
| MDA 0315 | Software |
| MDA 0316 | Medical gas supply systems and parts t |
| MDA 0317 | Active non-implantable devices for cle |
| MDA 0318 | Other active non-implantable devices |

**B. Non-active devices**

1. *Non-active implants and long term surgically invasive devices*

| MDN CODE | Non-active implants and long term surgically invasive devices |
|---|---|
| MDN 1101 | Non-active cardiovascular, vascular and neurovascular implants |
| MDN 1102 | Non-active osteo- and orthopaedic implants |
| MDN 1103 | Non-active dental implants and dental materials |
| MDN 1104 | Non-active soft tissue and other implants |

2. *Non-active non-implantable devices*

| MDN CODE | Non-active non-implantable devices |
|---|---|
| MDN 1201 | Non-active non-implantable devices for anaesthesia, emergency and intensive care |
| MDN 1202 | Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis |
| MDN 1203 | Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools |
| MDN 1204 | Non-active non-implantable devices for wound and skin care |
| MDN 1205 | Non-active non-implantable orthopaedic and rehabilitation devices |
| MDN 1206 | Non-active non-implantable ophthalmologic devices |
| MDN 1207 | Non-active non-implantable diagnostic devices |
| MDN 1208 | |
| MDN 1209 | |
| MDN 1210 | |

## ANNEX II

**The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of *in vitro* diagnostic medical devices under Regulation (EU) 2017/746**

**I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**

1. *Devices intended to be used for blood grouping*

| IVR CODE | Devices intended to be used to determine markers of the specific blood grouping systems to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration |
|---|---|
| IVR 0101 | Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] |
| IVR 0102 | Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] |
| IVR 0103 | Devices intended to determine markers of the Kell system [Kel1 (K)] |
| IVR 0104 | Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)] |
| IVR 0105 | Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)] |
| | **Other devices intended to be used for blood grouping** |
| IVR 0106 | Other devices intended to be used for blood grouping |

2. *Devices intended to be used for tissue typing*

| IVR CODE | Devices intended to be used for tissue typing |
|---|---|
| IVR 0201 | Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood compo administration |
| IVR 0202 | Other devices inten |

3. *Devices intended to be used for markers of can*

| IVR CODE | Devices inter |
|---|---|
| IVR 0301 | Devices intend |
| IVR 0302 | Other devices i |

4. *Devices intended to be used for human genetic*

| IVR CODE | Devices intended to b |
|---|---|
| IVR 0401 | Devices intended to be used in screer |
| IVR 0402 | Devices intended to be used to predi |
| IVR 0403 | Other devices intended to be used fo |

5. *Devices intended to be used to determine mark*

| IVR CODE | Devices intended to be use |
|---|---|
| IVR 0501 | Devices intended to be used transmissible agents |
| IVR 0502 | Devices intended to be used |

6. *Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures*

| IVR CODE | Devices intended to be used for a specific disease |
|---|---|
| IVR 0601 | Devices intended to be used for screening/confirmation of specific disorders/impairments |
| IVR 0602 | Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease |
| IVR 0603 | Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances |
| IVR 0604 | Other devices intended to be used for a specific disease |
| | **Devices intended to be used to define or monitor physiological status and therapeutic measures** |
| IVR 0605 | Devices intended to be used for monitoring of levels of medicinal products, substances or biological components |
| IVR 0606 | Devices intended to be used for non-infectious disease staging |
| IVR 0607 | Devices intended to be used for detection of pregnancy or fertility testing |
| IVR 0608 | Devices intended to be used for screening, determination or monitoring of physiological markers |
| IVR 0609 | Other devices intended to be used to define or monitor physiological status and therapeutic measures |

7. *Devices which are controls without a quantitative or qualitative assigned value*

| IVR CODE | Controls without a quantitative or qualitative assigned value |
|---|---|
| IVR 0701 | Devices which are controls without a quantitative assigned value |
| | tative assigned value |

NOTE: Regulations (EU) 2017/2185 used to specify the Notified Body's "Scope of Designation"

# **Article 16(4)** – Scope of Certificate: Types of Devices specified by their EMDN

European Medical Device Nomenclature

The EMDN is characterized by its alphanumeric structure that is established in a multi-level hierarchical tree.

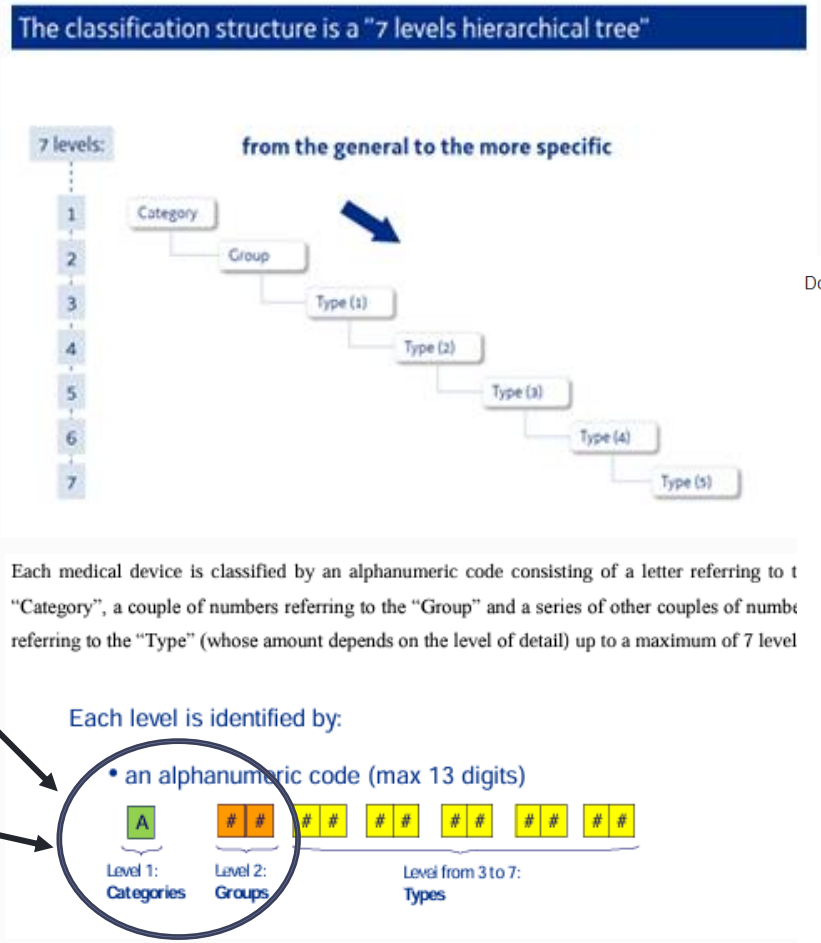
Article 16(4) Cert lists 1st +2nd level EMDN

1st Level = Device Category

- Is understood as the relevant MDN, MDA, IVR Code from Reg (EU) 2017/2185 in scope of NB

2nd level = Device Group Level

- Example: A01 – Needles




# **Article 16(4)** – Training Objectives

**Understand** the scope and requirements of Art16 (2, 3, 4) MDR/IVDR

**Identify** the types of organisations eligible for Art16(4) certification

**Understand** Conformity Assessment & Certification Process & Certification Cycle in BSI's Article 16(4) Certification Scheme

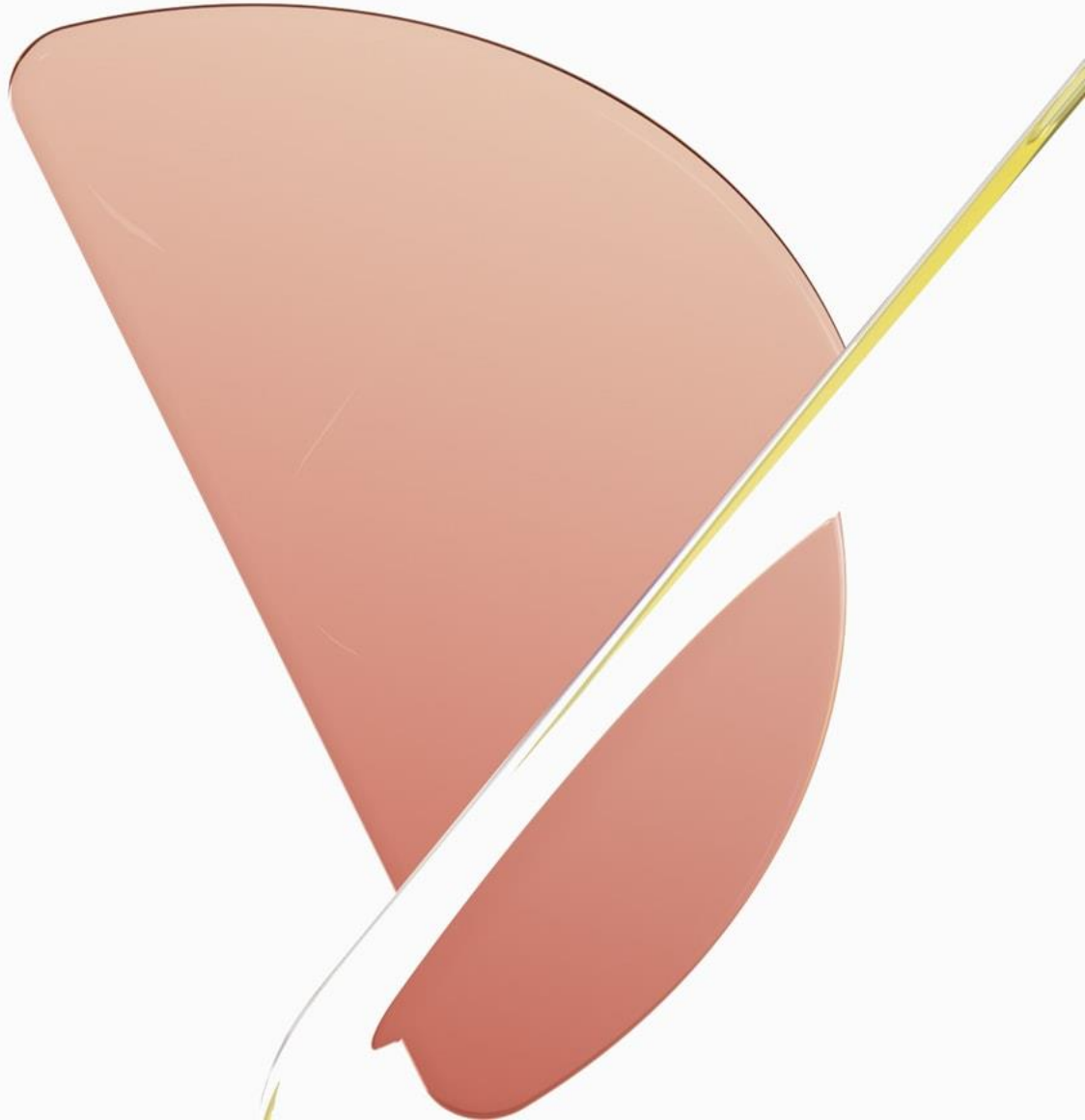
# Summary:

Importers / Distributors who conduct Relabelling and/or Repackaging activities as described in Article 16(2)  on devices that are certified under the MDR and/or the IVDR under a Quality Management System containing procedures that ensure the compliance with the Article 16(3) requirements, can apply with BSI for Article 16(4) Certification.

BSI is a Notified Body (NB2797) designated for MDR (full scope) and IVDR (full scope)

# Questions & Answers

# Thank you for listening



# **Article 16(4)** - Certificate Template (IVDR)

Internal

**Article 16(4) Certificate**
Regulation (EU) 2017/746, Article 16(4)

**IVDR XXXXXX RXXX**

**Name:**

**SRN:**

**Address:**
Number Street
Town
County
Country
Postal Code

For Distributors we will enter **"Not Available"** in SAP and for the certificate.
For Importers we will capture the SRN and it will appear on the certificate.

**Scope:**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746 Article 16(3), the quality system meets the requirements of the Regulations for the activities mentioned in Article 16(2).

For and on behalf of BSI, a Notified Body for the above Regulations (Notified Body Number 2797):

_____
Signature
Graeme Tunbridge, Senior Vice President Medical Devices

First issue Date: YYYY/MM/DD
Starting Validity Date: YYYY/MM/DD
Current Issue Date: YYYY/MM/DD
Expiry Date: YYYY/MM/DD



Internal

**Article 16(4) Certificate**
Regulation (EU) 2017/746, Article 16(4)

**IVDR XXXXXX RXXX**

**Device Schedule:**

| Device Group (EMDN Code and description) | Applicable IVDR Code (as per Commission Implementing Regulation (EU) 2017/2185) | Activity Type(s) |
|---|---|---|
| W01 REAGENTS | IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] | Relabelling |
| W01 REAGENTS | IVR 0102 Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] | Repackaging |
| W01 REAGENTS | IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)] | Relabelling & Repackaging |
| W02 IVD INSTRUMENTS | | |
| W05 IVD GENERIC USE CONSUMABLES | | |

First issue Date: YYYY/MM/DD
Starting Validity Date: YYYY/MM/DD
Current Issue Date: YYYY/MM/DD
Expiry Date: YYYY/MM/DD



Internal

**Article 16(4) Certificate**
Regulation (EU) 2017/746, Article 16(4)

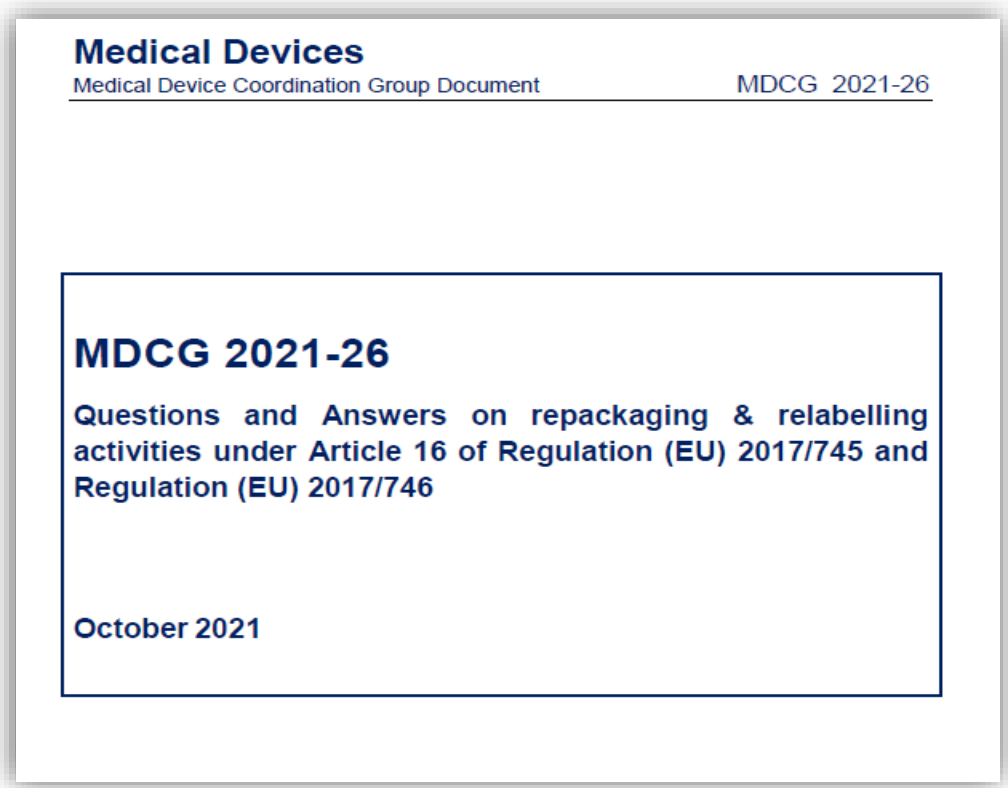
**IVDR XXXXXX RXXX**

**Certificate History**
(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

| Date | Reference Number | Action |
|---|---|---|
| Current | Xxxxxxx (Include SMO number without "SMO") | |

First issue Date: YYYY/MM/DD
Starting Validity Date: YYYY/MM/DD
Current Issue Date: YYYY/MM/DD
Expiry Date: YYYY/MM/DD

# **Article 16** – MDCG Guidance documents


Medical Devices
Medical Device Coordination Group Document MDCG 2021-26

MDCG 2021-26

Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746

October 2021

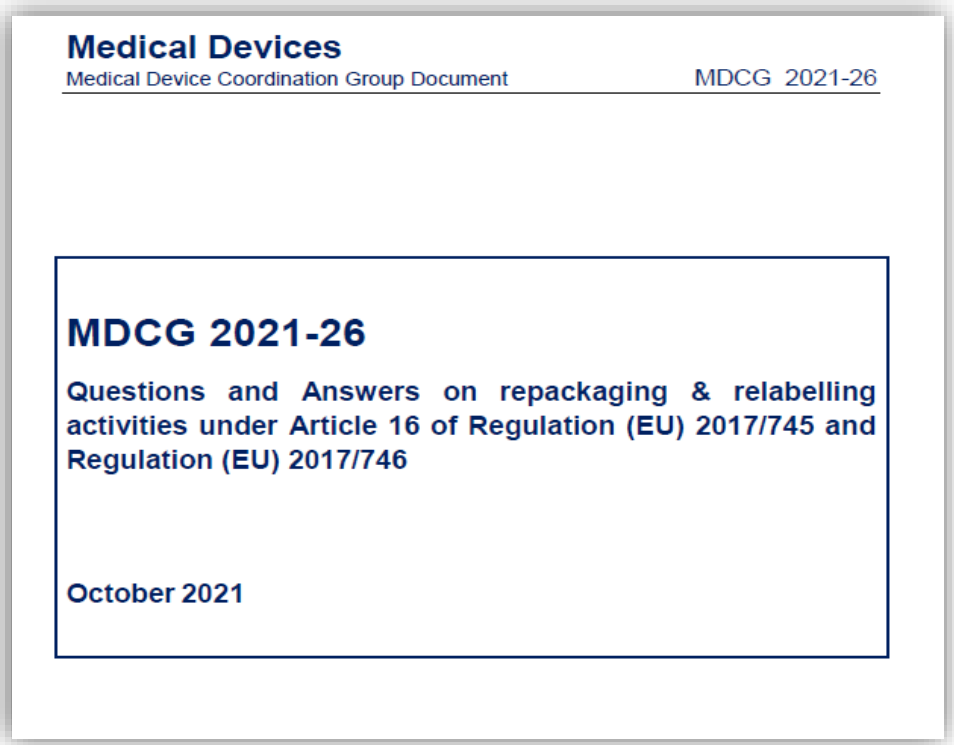
Guidance for Distributors & Importers

14 Questions / Answers

(Q2) Do 'legacy devices' need an Article 16(4) Certificate?

(Q3) What is meant by 'necessary in order to market' a modified device in the relevant Member State'?

# **Article 16** – MDCG Guidance documents



**Medical Devices**
Medical Device Coordination Group Document MDCG 2021-26

**MDCG 2021-26**

**Questions and Answers on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746**

**October 2021**

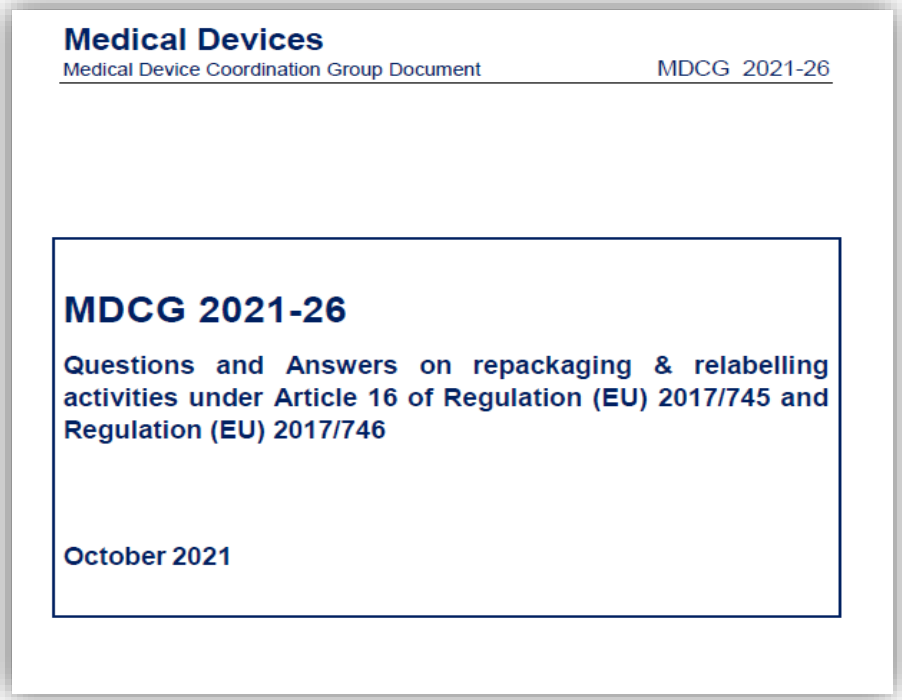
Guidance for Distributors & Importers

14 Questions / Answers

(Q5 & 6) What information should be notified to the manufacturer(s) / Competent Authorities according to the Article 16(4)?

(Q8) When should additional notification to manufacturer(s) & competent authorities be submitted?

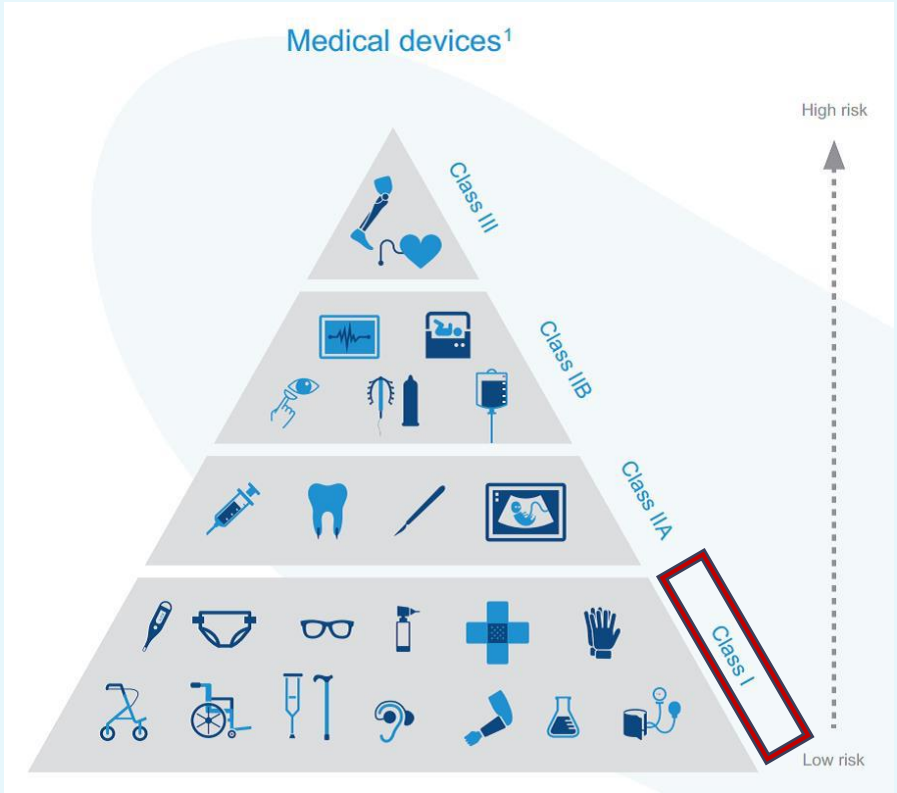
# **Article 16** – MDCG Guidance documents




Guidance for Distributors & Importers

14 Questions / Answers

(Q11) Do relabelling and/or repackaging activities performed on Class I devices & class A IVD devices also involve a notified body review?



# **Art 13 Importers & Art 14 Distributors** – General Obligations


NOTE: I&D shall always meet the “general obligations”

- Art 13 (Importers)
- Art 14 (Distributors)

Guidance provided in MDCG 2021-27