IVDR Conformity Assessment Routes

Guide

IVDR Conformity Assessment Routes

Notified Body Assessments
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Disclaimers:

• The information presented in this brochure is based on our current understanding of the IVDR requirements at the time of publishing and is subject to change

• The tables do not cover assessments under the conformity route of Annex XI (Production Quality Assurance). BSI is not designated to Annex X (Type Examination)

• The Competent Authority may ask for verification testing by the EU Reference Laboratory for devices other than Class D
Implementing rules

Rule 1
Transmissible Disease
Blood screening
High risk disease

Rule 2
Blood or tissue compatibility

Rule 3
Infectious disease
Cancer testing
Companion diagnostics
Genetic testing
Congenital screening

Note: When classifying your device, always consult the IVDR and, in particular, Annex VIII.
Annex VIII of the IVDR

All near patient tests are classified in their own right, they can be D, C, or B, depending on intended purpose.

Class B self-tests
- Pregnancy tests
- Fertility tests
- Cholesterol tests
- Detection of glucose, erythrocytes, leucocytes and bacteria in urine
Useful definitions

**CE 0086 and CE 2797**
Throughout this guide, our Notified Bodies are referenced using their assigned Notified Body number: BSI UK Notified Body (0086) and BSI Netherlands Notified Body (2797).

**Common Specifications**
The European Commission provides Common Specifications to the IVDR as a means of complying with the legal obligations applicable to a device, process or system, such as the General Safety and Performance Requirements (GSPRs), the requirements for performance studies and performance evaluation, and/or post-market surveillance.

**CA and EMA**
In the case of companion diagnostics, the Competent Authority (CA) or the European Medicines Agency (EMA) will be consulted regarding the associated medicinal product.

**EU Reference Laboratory**
These have been introduced under the IVDR and are laboratories designated by the European Commission to support with the assessment of Class D IVD devices. An EU Reference Laboratory is responsible for verifying the performance of Class D IVD devices and the ongoing verification of manufactured devices.

The Competent Authority may ask for verification testing by the EU Reference Laboratory for devices other than Class D.

**Notified Body (NB)**
The role of BSI as a Notified Body is to conduct a conformity assessment under the IVDR. This usually requires an audit of the manufacturer’s quality management system and, depending on the particular classification of the device, a review of the relevant Technical Documentation in support of the safety and performance claims for the device. The Technical Documentation is assessed against the General Safety and Performance Requirements (GSPR) within the IVDR.
Class A devices

Note: No Notified Body involvement

Class A (excluding sterile devices)

Annex II and III
Technical Documentation

Declaration of conformity (Annex IV)
Self declaration

CE Marking (Annex V)
CE
**Class A sterile devices**

- **Class A sterile**
- **Annex II and III**
  - Technical Documentation
- **Annex IX**
  - QMS
  - Chapters I, III
- **Annex XI**
  - Production Quality Assurance
- Declaration of conformity
  - (Annex IV)
- CE Marking
  - (Annex V)
  - CE 0086 or CE 2797

* Limited to sterility aspects
Class A sterile devices

<table>
<thead>
<tr>
<th></th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y1</td>
<td>Y2</td>
</tr>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>N/A</td>
<td>N/A</td>
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</table>

Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) | Not required for NB assessment


Post Market Surveillance (PMS) Report (Article 80) | Updated when necessary and made available to the NB upon request.

Periodic Safety Update Report (PSUR) (Article 81) | N/A| N/A| N/A| N/A| N/A|

Unannounced Audits | At least once every 5 years

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class B devices
(excluding self-testing and near-patient testing (NPT) devices)

Class B
(excluding class B self-testing and near-patient testing)

Annex IX QMS
Chapters I, III

Annex IX Chapter II
Technical Documentation assessed per device category (Section 4)

Declaration of conformity
(Annex IV)

CE Marking
(Annex V)
CE 0086 or CE 2797
### Class B devices (excluding self-testing and NPT devices)

<table>
<thead>
<tr>
<th>Class B devices (excluding self-testing and NPT devices)</th>
<th>Initial Conformity Assessment</th>
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<tr>
<td></td>
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<td>Y1</td>
</tr>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits (if sterile)</td>
<td>N/A</td>
<td>Yes (if sterile)</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Sample per device category</td>
<td>As per the Technical Documentation Sampling Plan. A Technical Documentation surveillance audit is required every year whilst there are still devices left to be reviewed under the certificate scope.</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
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<td>N/A</td>
</tr>
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<td>Summary of Safety and Performance (Article 29)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)</td>
<td>Updated as per Manufacturer’s Performance Evaluation Plan; NB to review as per Technical Documentation Sampling Plan</td>
<td></td>
</tr>
<tr>
<td>Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B)</td>
<td>Updated as per Manufacturer’s PMS, PMPF plans; NB to review as per Technical Documentation Sampling Plan. Implementation of the PMPF plan will be verified during annual surveillance visits</td>
<td></td>
</tr>
<tr>
<td>Post Market Surveillance (PMS) Report (Article 80)</td>
<td>Updated when necessary and provided to the CA and/or NB upon request</td>
<td></td>
</tr>
<tr>
<td>Periodic Safety Update Report (PSUR) (Article 81)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
<td></td>
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* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The **Recertification** indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
**Class B** self-testing and NPT devices

- **Class B** self-testing and near-patient testing
- **Annex IX QMS**
  - Chapters I, III
- **Annex IX Chapter II**
  - Technical Documentation assessed for every device
  - (Sections 4 and 5.1)
- **Declaration of conformity**
  - (Annex IV)
- **CE Marking**
  - (Annex V)
  - CE 0086 or CE 2797
Class B devices self-testing and NPT devices

<table>
<thead>
<tr>
<th>Class B devices self-testing and NPT devices</th>
<th>Initial Conformity Assessment</th>
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<tbody>
<tr>
<td></td>
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<td>Yes</td>
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<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
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<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
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<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
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</tr>
<tr>
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<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) Updated as per Manufacturer's Performance Evaluation Plan; NB to review at the time of substantial change reviews

Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B) Updated as per Manufacturer’s PMS, PMPF plans; NB to review at the time of substantial change reviews

Post Market Surveillance (PMS) Report (Article 80) Updated when necessary and provided to the CA upon request. NB to review at time of substantial change reviews

Periodic Safety Update Report (PSUR) (Article 81) N/A N/A N/A N/A N/A

Unannounced Audits At least once every 5 years

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class C devices
(excluding self-testing, NPT and companion diagnostics (CDx))

Class C
(excluding self-testing, near-patient testing and companion diagnostics)

Annex IX QMS
Chapters I, III

Annex IX Chapter II
Technical Documentation assessed per generic device group (Section 4)

Declaration of conformity
(Annex IV)

CE Marking
(Annex V)
CE 0086 or CE 2797
## Class C devices (excluding self-testing, NPT and companion diagnostics (CDx))

<table>
<thead>
<tr>
<th>Class C devices (excluding self-testing, NPT and CDx devices)</th>
<th>Initial Conformity Assessment</th>
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<td>QMS Audits</td>
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<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Sample per generic device group</td>
<td>As per the Technical Documentation Sampling Plan. A Technical Documentation surveillance audit is required every year whilst there are still devices left to be reviewed under the certificate scope.</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
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<td>Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B)</td>
<td>Updated as per Manufacturer's PMS, PMPF plans; NB to review as per Technical Documentation Sampling Plan. NB QMS audits to verify implementation of the plan by sampling complaints, vigilance information etc.</td>
<td></td>
</tr>
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<td>Post Market Surveillance (PMS) Report (Article 80)</td>
<td>Post-market surveillance will be captured in the Periodic Safety Update Report</td>
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<tr>
<td>Periodic Safety Update Report (PSUR) (Article 81)</td>
<td>PSUR update required at least annually. The PSUR should be available to the NB upon request</td>
<td></td>
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<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
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**Class C** self-testing and NPT devices

- **Class C** self-testing and near-patient testing
- **Annex IX QMS**
  - Chapters I, III
- **Annex IX Chapter II**
  - Technical Documentation assessed for every device
    - (Sections 4 and 5.1)
- **Declaration of conformity**
  - (Annex IV)
- **CE Marking**
  - (Annex V)
  - CE 0086 or CE 2797
Class C devices self-testing and NPT devices

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<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>Yes</td>
<td>Updated as soon as possible, where necessary</td>
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Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) | Updated at least annually; NB to review at the time of PSUR reviews or substantial change reviews

Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B) | Updated as per Manufacturer's PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews

Post Market Surveillance (PMS) Report (Article 80) | Post-market surveillance will be captured in the Periodic Safety Update Report

Periodic Safety Update Report (PSUR) (Article 81) | PSUR update required at least annually. The PSUR should be available to the NB upon request

Unannounced Audits | At least once every 5 years

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The **Y3 Recertification** indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class C companion diagnostic (CDx) devices

1. **Class C companion diagnostic**
2. **Annex IX QMS**
   - Chapters I, III
3. **Annex IX Chapter II**
   - Technical Documentation assessed for every device (Sections 4 and 5.2)
4. **CA or EMA consultation**
   - as per Annex IX – Section 5.2
5. **Declaration of conformity (Annex IV)**
6. **CE Marking**
   - (Annex V)
   - CE 0086 or CE 2797
Class C companion diagnostic (CDx) devices

<table>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits (if sterile)</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>Yes</td>
<td>Modifications to the devices may need supplementary consultations (determined on a case-by-case basis taking into account the nature of the changes proposed)</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
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<td>Updated as soon as possible, where necessary</td>
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Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) | Updated at least annually; NB to review at the time of PSUR reviews or substantial change reviews
Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B) | Updated as per Manufacturer's PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews
Post Market Surveillance (PMS) Report (Article 80) | Post-market surveillance will be captured in the Periodic Safety Update Report
Periodic Safety Update Report (PSUR) (Article 81) | PSUR update required at least annually. The PSUR should be available to the NB upon request
Unannounced Audits | At least once every 5 years

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The Y3 Recertification indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class D with Common Specification (excluding CDx)

- **Annex IX QMS**
  - Chapters I, III

- **Annex IX Chapter II**
  - excluding Section 5*
  - Technical Documentation assessed for every device

- **Verification by EU Reference Laboratory**
  - Annex IX – Section 4.9§

- **Declaration of conformity**
  - (Annex IV)

- **CE Marking**
  - (Annex V)
  - CE 0086 or CE 2797

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* For self-test and NPT Section 5.1 is included

§ Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100
### Class D with Common Specification (excluding CDx)

<table>
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<tr>
<th>Class D with Common Specification (excluding CDx)</th>
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<th>Surveillance</th>
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<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>Yes</td>
<td>Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed)</td>
</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>Yes</td>
<td>Updated as soon as possible, where necessary</td>
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</tbody>
</table>

Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) | Updated at least annually. NB to review at the time of PSUR reviews or substantial change reviews |
Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B) | Updated as per Manufacturer's PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews |
Post Market Surveillance (PMS) Report (Article 80) | Post-market surveillance will be captured in the Periodic Safety Update Report |
Periodic Safety Update Report (PSUR) (Article 81) | PSUR update required at least annually; submitted to the NB via EUDAMED for NB review |
Unannounced Audits | At least once every 5 years |

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The **Y3 Recertification** indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class D with no Common Specification
(excluding CDx)

Class D with no Common Specification
(excluding CDx)

Annex IX QMS
Chapters I, III

Annex IX Chapter II excluding Section 5*
Technical Documentation assessed for every device

Verification by EU Reference Laboratory
Annex IX – Section 4.9§

Expert consultation†
(Article 48(6))

Declaration of conformity
(Annex IV)

CE Marking
(Annex V)
CE 0086 or CE 2797

* For self-test and NPT Section 5.1 is included

§ Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100

† Where no Common Specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type
## Class D with no Common Specification (excluding CDx)

<table>
<thead>
<tr>
<th>Class D with no Common Specification (excluding CDx)</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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<tbody>
<tr>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits (if sterile)</td>
<td>N/A</td>
<td>Yes (if sterile)</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>Yes, if the device is the first of its type</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>Yes</td>
<td>Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed)</td>
</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>Yes</td>
<td>Updated as soon as possible, where necessary</td>
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</table>

| Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56) | Updated at least annually. NB to review at the time of PSUR reviews or substantial change reviews |
| Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B) | Updated as per Manufacturer's PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews |
| Post Market Surveillance (PMS) Report (Article 80) | Post-market surveillance will be captured in the Periodic Safety Update Report |
| Periodic Safety Update Report (PSUR) (Article 81) | PSUR update required at least annually; submitted to the NB via EUDAMED for NB review |
| Unannounced Audits                                  | At least once every 5 years  |

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The **Recertification** indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
Class D CDx devices

Annex IX QMS
Chapters I, III

Annex IX Chapter II
including Section 5.2
Technical Documentation assessed for every device

CA or EMA consultation
– Annex IX, Section 5.2

Verification by EU Reference Laboratory
Annex IX – Section 4.9\(^{6}\)

Expert consultation\(^{†}\)
(Article 48(6))

Declaration of conformity
(Annex IV)

CE Marking
(Annex V)
CE 0086 or
CE 2797

\(^{6}\) Required for devices for which one or more EU Reference Laboratories have been designated in accordance with Article 100

\(^{†}\) Where no Common Specification is available, the NB shall provide the performance evaluation report of the manufacturer to the Expert Panel within five days of receipt. Required in cases where the device is the first of its type
<table>
<thead>
<tr>
<th>Class D CDx devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Y1</td>
<td>Y2</td>
</tr>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile) N/A</td>
<td>Yes (if sterile) N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>Yes</td>
<td>Modifications to the devices may need supplementary consultations (determined on a case-by-case basis taking into account the nature of the changes proposed)</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>Yes, if no CS and the device is the first of its type</td>
<td>N/A</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>Yes</td>
<td>Modifications to the devices may need supplementary verifications (determined on a case-by-case basis taking into account the nature of the changes proposed)</td>
</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>Yes</td>
<td>Updated as soon as possible, where necessary.</td>
</tr>
</tbody>
</table>

- **Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)**: Updated at least annually; the NB will provide it to the expert panel as needed. NB to review at the time of PSUR reviews or substantial change reviews.
- **Post Market Performance Follow-up (PMPF) Evaluation Report updates (Article 56 and Annex XIII, Part B)**: Updated as per Manufacturer's PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews.
- **Post Market Surveillance (PMS) Report (Article 80)**: Post-market surveillance will be captured in the Periodic Safety Update Report.
- **Periodic Safety Update Report (PSUR) (Article 81)**: PSUR update required at least annually; submitted to the NB via EUDAMED for NB review.
- **Unannounced Audits**: At least once every 5 years.

* QMS certificates are valid for three years, whilst CE certificates remain valid for a maximum of five years. The **Y3 Recertification** indicated in the table relates to the EN ISO 13485:2016 certificate cycle. Certification cycles vary and re-certification may not always occur at Y3.
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