Class Is/Im/Ir devices
Class IIa devices
Class IIb Annex VIII rule 12 devices
Class IIb implantable – Well-Established Technologies (WET)
Class IIb non-implantable non rule 12 devices (non WET)
Class IIb implantable devices (excluding WET)
Class III non-implantable devices
Class III implantable devices
Custom-made Class III implantable devices
Custom-made devices (excluding custom-made Class III implantable devices)
Class I devices (excluding Class Is/Im/Ir devices)

DISCLAIMERS:
Information presented in the conformity assessment flow charts and tables below is based on our current understanding of the MDR requirements at the time of publishing this document; subject to change. The tables do not cover assessments under the conformity routes Annex X (Type Examination) and Annex XI Part B (Product Verification) which may require additional tests or examinations of the devices. The tables present a generalization of the requirements based on the classification of devices and some exceptions may apply.

IVDR Conformity Assessment Routes Guide

IVDR Conformity Assessment Routes
Notified Body Assessments

Inspiring trust for a more resilient world.
Contents

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Class C devices (excluding self-testing, NPT and companion diagnostics (CDx)) 14
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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
Illustration of the Classification rules as per Annex VIII of the IVDR

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.
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

Annex VIII of the IVDR
Useful definitions

CE 2797
Throughout this guide, our Notified Body is referenced using its assigned Notified Body number: BSI The Netherlands (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 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 2797

* Limited to sterility aspects
# Class A sterile devices

<table>
<thead>
<tr>
<th>Class A sterile devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<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</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>N/A</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>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>
</tr>
<tr>
<td>Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)</td>
<td>Not required for NB assessment</td>
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<tr>
<td>Post Market Surveillance (PMS) Report (Article 80)</td>
<td>Updated when necessary and made available to the 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>
</tr>
</tbody>
</table>

* 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 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>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Y1</td>
</tr>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<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>Sample per device category</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></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>
<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>
<tr>
<td>Performance Evaluation Report updates</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) updates Evaluation Report (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>
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</table>

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 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 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>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>QMS Audits</td>
<td>Y1</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
</tr>
<tr>
<td></td>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
</tr>
<tr>
<td></td>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
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<tr>
<td></td>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Summary of Safety and Performance (Article 29)</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) updates Evaluation Report (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 | 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 devices (excluding self-testing, NPT and companion diagnostics (CDx))

<table>
<thead>
<tr>
<th>Class C devices (excluding self-testing, NPT and CDx devices)</th>
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<th>Surveillance</th>
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</thead>
<tbody>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>Yes</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>
</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>Yes</td>
<td>Updated as soon as possible, where necessary</td>
</tr>
<tr>
<td>Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)</td>
<td>Updated at least annually; NB to review as per Technical Documentation Sampling Plan</td>
<td></td>
</tr>
<tr>
<td>Post Market Performance Follow-up (PMPF) updates Evaluation Report (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>
<tr>
<td>Post Market Surveillance (PMS) Report (Article 80)</td>
<td>Post-market surveillance will be captured in the Periodic Safety Update Report</td>
<td></td>
</tr>
<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>
</tr>
<tr>
<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
<td></td>
</tr>
</tbody>
</table>

* 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 self-testing and NPT devices

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 2797
### Class C devices self-testing and NPT devices

<table>
<thead>
<tr>
<th>Class C self-testing and NPT devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Y1, Y2, Y3, Y4, Y5</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>Y1, Y2, Y3, Y4, Y5</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>Y1, Y2, Y3, Y4, Y5</td>
</tr>
<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
<td>N/A</td>
<td>Y1, Y2, Y3, Y4, Y5</td>
</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
<td>N/A</td>
<td>Y1, Y2, Y3, Y4, Y5</td>
</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>N/A</td>
<td>Y1, Y2, Y3, Y4, Y5</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; NB to review at the time of PSUR reviews or substantial change reviews
- Post Market Performance Follow-up (PMPF) updates Evaluation Report (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

Annex IX QMS
Chapters I, III

Annex IX Chapter II
Technical Documentation assessed for every device (Sections 4 and 5.2)

CA or EMA consultation
as per Annex IX – Section 5.2

Declaration of conformity (Annex IV)

CE Marking
(Annex V)
CE 2797
## Class C companion diagnostic (CDx) devices

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<thead>
<tr>
<th>Class C companion diagnostic (CDx) devices</th>
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<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
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<tr>
<td><strong>QMS Audits</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td><strong>Microbiology Audits</strong></td>
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<tr>
<td><strong>Technical Documentation Assessment</strong></td>
<td>Review for every device</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Recertification</td>
<td></td>
</tr>
<tr>
<td><strong>Competent Authority or EMA consultation (Annex IX, Section 5.2)</strong></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>
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<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Experts consultations (article 48(6))</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td><strong>Verification by EU reference laboratory (Annex IX, section 4.9)</strong></td>
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<td>N/A</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td><strong>Summary of Safety and Performance (Article 29)</strong></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) updates Evaluation Report (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 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
<table>
<thead>
<tr>
<th>Class D with Common Specification (excluding CDx)</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
<th>Y1</th>
<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
<th>Y5</th>
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</thead>
<tbody>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Recertification*</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
<td>N/A</td>
<td>Yes (if sterile)</td>
<td>N/A</td>
<td>Yes (if sterile)</td>
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<td>N/A</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Recertification</td>
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<tr>
<td>Competent Authority or EMA consultation (Annex IX, Section 5.2)</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td>Experts consultations (article 48(6))</td>
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<td>N/A</td>
<td>N/A</td>
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<td>N/A</td>
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</tr>
<tr>
<td>Verification by EU reference laboratory (Annex IX, section 4.9)</td>
<td>Yes</td>
<td></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>
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</tr>
<tr>
<td>Summary of Safety and Performance (Article 29)</td>
<td>Yes</td>
<td></td>
<td>Updated as soon as possible, where necessary</td>
<td></td>
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<td></td>
<td></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) updates Evaluation Report (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)**

- **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 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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Y1</td>
</tr>
<tr>
<td>QMS Audits</td>
<td>Yes</td>
<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>
</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>
</tr>
<tr>
<td>Performance Evaluation Report updates (Annex XIII - Part A, Section 1.3.2 and Article 56)</td>
<td>Updated at least annually. NB to review at the time of PSUR reviews or substantial change reviews</td>
<td></td>
</tr>
<tr>
<td>Post Market Performance Follow-up (PMPF) updates Evaluation Report (Article 56 and Annex XIII, Part B</td>
<td>Updated as per Manufacturer’s PMS, PMPF plans; NB to review at the time of PSUR reviews or substantial change reviews</td>
<td></td>
</tr>
<tr>
<td>Post Market Surveillance (PMS) Report (Article 80)</td>
<td>Post-market surveillance will be captured in the Periodic Safety Update Report</td>
<td></td>
</tr>
<tr>
<td>Periodic Safety Update Report (PSUR) (Article 81)</td>
<td>PSUR update required at least annually; submitted to the NB via EUDAMED for NB review</td>
<td></td>
</tr>
<tr>
<td>Unannounced Audits</td>
<td></td>
<td>At least once every 5 years</td>
</tr>
</tbody>
</table>

* 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 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§

- **Expert consultation†**
  - (Article 48(6))

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

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

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§ 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 CDx devices

<table>
<thead>
<tr>
<th>Class D CDx devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Y1</td>
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<td>QMS Audits</td>
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<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>
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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) updates Evaluation Report (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

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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

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