MDR Conformity Assessment Routes
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DISCLAIMER:
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.
Class Is/Im/Ir devices

** Class Ir (Class I re-usable surgical instruments)
* Limited to sterility, metrology or re-use aspects as applicable

Keep the following text as readable as possible:

### Class Is/Im/Ir devices

** Class Is, Im, Ir**

- Annex II and III Technical Documentation
- Annex IX* QMS Chapters I, III
- Annex XI* – Part A Production Quality Assurance
- Declaration of conformity (Annex IV)

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#### CE marking (Annex V)

** CE 2797 **

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### Applicable audits, assessments and requirements

#### Class Is/Im/Ir devices

<table>
<thead>
<tr>
<th>Class Is/Im/Ir devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QMS Audits</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Microbiology Audits</strong></td>
<td>Yes*</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Technical Documentation Assessment</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Clinical Evaluation Consultation Procedure (Article 54)</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Consultations (Rule 14, Rule 18, Rule 21)</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Summary of Safety and Clinical Performance (Article 32)</strong></td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
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<th>Y2</th>
<th>Y3</th>
<th>Y4</th>
<th>Y5</th>
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<td>Yes</td>
<td>Recert**</td>
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<td>Yes*</td>
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</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**

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**Declaration of conformity (Annex IV)**

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**CE marking (Annex V)**

** CE 2797 **

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** If sterile or re-usable surgical instruments
** If sterile or re-usable surgical instruments

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** CE marking (Annex V) **

** CE 2797 **
### Class IIa devices

- **Annex IX QMS**
  - Chapters I, III
- **Annex XI – Part A**
  - Production Quality Assurance
- **Annex XI – Part B**
  - Production Verification
- **Annex IX Chapter II**
  - Technical Documentation
  - Assessed per device category
- **Annex II and Annex III**
  - Technical Documentation
  - Assessed per device category
- **Declaration of conformity**
  - (Annex IV)
- **CE marking**
  - (Annex V)
  - CE 2797

### Applicable audits, assessments and requirements

#### Class IIa non-implantable devices

<table>
<thead>
<tr>
<th></th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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</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>
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<tr>
<td>Technical Documentation Assessment</td>
<td>Sample per category of devices</td>
<td>As per the Technical Documentation Sampling Plan</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Clinical Evaluation Report updates</td>
<td>Updated as per manufacturer's clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan</td>
<td></td>
</tr>
<tr>
<td>Post Market Clinical Follow-Up Update Report (Article 61)</td>
<td>Updated as per manufacturer’s PMS, PMCF plans. Notified Body to review as per Technical Documentation Sampling Plan</td>
<td></td>
</tr>
<tr>
<td>Periodic Safety Update Report (Article 86)</td>
<td>PSUR update required at least once every 2 years. Notified Body to review as per Technical Documentation Sampling Plan</td>
<td></td>
</tr>
<tr>
<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
<td></td>
</tr>
</tbody>
</table>

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* If sterile
** 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.
### Applicable audits, assessments and requirements

**Class IIa implantable devices**

<table>
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<th>Class IIa implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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<tbody>
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<td></td>
<td></td>
<td>Y1</td>
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<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>Sample per category of devices</td>
<td>As per the Technical Documentation Sampling Plan</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
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</tbody>
</table>

- Updated at least annually “if indicated”. Notified Body to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments

---

<table>
<thead>
<tr>
<th>Clinical Evaluation Report updates</th>
<th>Updated as per manufacturer’s clinical evaluation plan. Notified Body to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Market Clinical Follow-Up Update Report (Article 61)</td>
<td>Updated at least annually. Notified Body to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments</td>
</tr>
<tr>
<td>Periodic Safety Update Report (Article 86)</td>
<td>Updated when necessary and at least every two years. submitted to Notified Body via EUDAMED for Notified Body review</td>
</tr>
<tr>
<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
</tr>
</tbody>
</table>

- If sterile

**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 IIb Annex VIII Rule 12 devices

**Annex IX Chapter II**
- Technical Documentation
  - Assessed per generic device group

**Annex X**
- Type Examination
  
**Annex XI – Part A**
- Production Quality Assurance

**Annex XI – Part B**
- Production Verification

**Clinical Evaluation Consultation Procedure**
- Annex IX Sec 5 / Annex X Sec 6

**Declaration of conformity (Annex IV)**

Class IIb Annex VIII Rule 12 devices

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

**Annex IX Chapter II**
- Technical Documentation
  - Assessed per generic device group

**Annex X**
- Type Examination

**Class IIb Annex VIII Rule 12 devices**

Applicable audits, assessments and requirements
Class IIb Annex VIII Rule 12 devices

Annex VIII Rule 12 devices – All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body.

<table>
<thead>
<tr>
<th>Class IIb Annex VIII Rule 12 devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surveillance</strong></td>
<td>Y1</td>
<td>Y2</td>
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<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>Sample per generic device group</td>
<td>As per the Technical Documentation Sampling Plan</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
<td>Yes, but exemptions may apply as per Article 54.2</td>
<td>May be required if any modifications to the device adversely affect the risk-benefit ratio</td>
</tr>
<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
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</table>

- **Clinical Evaluation Report updates**
  - Updated as per manufacturer’s clinical evaluation plan. Notified Body to review updates as per Technical Documentation Sampling Plan

- **Post Market Clinical Follow-Up Update Report (Article 61)**
  - Updated as per manufacturer’s PMCF plan. Notified Body to review updates as per Technical Documentation Sampling Plan

- **Periodic Safety Update Report (Article 86)**
  - Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan

- **Unannounced Audits**
  - At least once every 5 years

* If sterile
** 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 IIb implantable WET
Class IIb non-implantable non Rule 12 non WET

Class IIb implantable WET
Class IIb non-implantable non Rule 12 non WET

Annex IX QMS
Chapters I, III

Annex X
Type Examination

Annex XI – Part A
Production Quality Assurance

Annex XI – Part B
Production Verification

Declaration of conformity
(Annex IV)

CE marking
(Annex V)
CE 2797

Applicable audits, assessments and requirements
Class IIb implantable wet

Well-Established Technologies (WET) - sutures, staples, dental fillings and braces, tooth crowns, screws, wedges, plates, wires, pins, clips & connectors as per Article 52 of MDR.

<table>
<thead>
<tr>
<th>Class IIb implantable WET 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*</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</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
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<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
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Clinical Evaluation Report updates
Updated as per manufacturer’s clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan

Post Market Clinical Follow-Up Update Report (Article 61)
Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments

Periodic Safety Update Report (Article 86)
Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review (assuming WET devices are implantable devices)

Unannounced Audits
At least once every 5 years

* If sterile
** 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

Continues on page 12
Applicable audits, assessments and requirements
Class IIb non-implantable non-WET non-Rule 12 devices

<table>
<thead>
<tr>
<th>Class IIb non-implantable non-WET non-Rule 12 devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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</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*</td>
<td>N/A</td>
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<td>Technical Documentation Assessment</td>
<td>Sample per generic device group</td>
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<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
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Clinical Evaluation Report updates
Updated as per manufacturer’s clinical evaluation plan. Notified Body to review as per Technical Documentation Sampling Plan

Post Market Clinical Follow-Up Update Report (Article 61)
Updated as per manufacturer’s PMCF plan. Notified Body to review updates as per Technical Documentation Sampling Plan

Periodic Safety Update Report (Article 86)
Updated at least annually. Notified Body to review updates as per Technical Documentation Sampling Plan

Unannounced Audits
At least once every 5 years

* If sterile

** 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 IIb implantable devices
Excluding WET

Class IIb implantable devices non-WET

Annex IX QMS Chapters I, III
Annex X Type Examination
Annex XI – Part A Production Quality Assurance
Annex XI – Part B Production Verification
Declaration of conformity (Annex IV)

CE marking (Annex V) CE 2797

Applicable audits, assessments and requirements
Class IIb implantable non-WET devices

<table>
<thead>
<tr>
<th>Class IIb implantable non-WET devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
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<td>Y2</td>
</tr>
<tr>
<td>QMS Audits</td>
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<tr>
<td>Microbiology Audits</td>
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<td>N/A</td>
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<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
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<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>N/A</td>
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<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
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<td>N/A</td>
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<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
<td>Updated at least annually “if indicated”. Notified Body to review at the time of PSUR reviews or substantial change reviews</td>
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Clinical Evaluation Report updates
Updated as per manufacturer’s clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews

Post Market Clinical Follow-Up Update Report (Article 61)
Updated at least annually. Notified Body to review at the time of PSUR reviews or substantial change reviews

Periodic Safety Update Report (Article 66)
Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review

Unannounced Audits
At least once every 5 years

* If sterile
** 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 III non-implantable devices**

**Class III non-implantable devices**

- **Annex IX QMS Chapters I, III**
- **Annex X Type Examination**
- **Annex IX Chapter II Technical Documentation for every device**
- **Annex XI – Part A Production Quality Assurance**
- **Annex XI – Part B Production Verification**
- **Declaration of conformity (Annex IV)**
- **CE marking (Annex V) CE 2797**

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**Applicable audits, assessments and requirements Class III non-implantable devices**

Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

<table>
<thead>
<tr>
<th>Class III non-implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>QMS Audits</td>
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<td>Y1, Y2, Y3</td>
</tr>
<tr>
<td>Microbiology Audits</td>
<td>Yes*</td>
<td>Y4, Y5</td>
</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>Y4, Y5</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation</td>
<td>N/A</td>
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</tr>
<tr>
<td>Procedure (Article 54)</td>
<td>N/A</td>
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</tr>
<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
<td>If applicable</td>
<td></td>
</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
<td></td>
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</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 III implantable devices

Class III implantable devices

Annex IX QMS Chapters I, III

Annex X Type Examination

Annex IX Chapter II Technical Documentation for every device

Annex XI – Part A Production Quality Assurance

Annex XI – Part B Production Verification

Declaration of conformity (Annex IV)

CE marking (Annex V) CE 2797

Applicable audits, assessments and requirements
Class III implantable devices

Including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.

<table>
<thead>
<tr>
<th>Class III implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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<tbody>
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<td></td>
<td>Y1</td>
<td>Y2</td>
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<tr>
<td>QMS Audits</td>
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<td>Microbiology Audits</td>
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<tr>
<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
<td>N/A</td>
</tr>
<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
<td>Yes, but exemptions may apply as per Article 54.2</td>
<td>May be required if any modifications to the device adversely affect the risk-benefit ratio</td>
</tr>
<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
<td>If applicable</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>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
<td>Updated at least annually ‘if indicated’. Notified Body to review at the time of PSUR assessments or substantial change reviews</td>
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Clinical Evaluation Report updates
Updated as per manufacturer’s clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews

Post Market Clinical Follow-Up Update Report (Article 61)
Updated at least annually. Notified Body review at the time of PSUR reviews or substantial change reviews

Periodic Safety Update Report (Article 86)
Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review

Unannounced Audits
At least once every 5 years

* If sterile
** 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
Custom-made Class III implantable devices

**Annex XIII**
- Documentation

**Annex IX**
- QMS
  - Chapters I

**Annex XI – Part A**
- Production Quality Assurance

**Statement**
- Annex XIII Section 1

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**CE Certificate issued**
- CE 2797

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### Applicable audits, assessments and requirements

**Custom-made Class III implantable devices**

<table>
<thead>
<tr>
<th>Custom-made Class III implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>Surveillance</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
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</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>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
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<td>Summary of Safety and Clinical Performance (Article 32)</td>
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<tr>
<td>Clinical Evaluation Report updates</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Post Market Clinical Follow-Up Update Report (Article 61)</td>
<td>As per manufacturer’s PMS, PMCF plans. Notified Body QMS audits to verify implementation of the plan</td>
<td></td>
</tr>
<tr>
<td>Periodic Safety Update Report (Article 86)</td>
<td>Updated at least annually. Not required to be submitted to EUDAMED for Notified Body review. Notified Body to verify updates at the time of surveillance QMS audits</td>
<td></td>
</tr>
<tr>
<td>Unannounced Audits</td>
<td>At least once every 5 years</td>
<td></td>
</tr>
</tbody>
</table>

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* If sterile
** 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.
**Custom-made devices**  
Excluding custom-made Class III implantable devices

- **Custom-made**
  - Annex XIII  
    - Documentation
  - Collect PMS, PMCF data as per Part B of Annex XIV
  - Statement  
    - Annex XIII Section 1

**Note:** No Notified Body involvement except for custom-made Class III implantable devices

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**Class I devices**  
Excluding Class Is, Ir, Im devices

- **Class I**
  - Annex II and III  
    - Technical Documentation
  - Declaration of conformity (Annex IV)
  - CE marking (Annex V)

**Note:** No Notified Body involvement
How BSI supports your Medical Devices launch

**Readiness**
In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We support you through the application and certification process.

**Worldwide Access**
We offer a wide range of regulatory and quality management programs that work cohesively for international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized certification body in Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP auditing organization for all participating regulatory authorities.

**BSI Transfer**
We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

**Additional Services**
- Access to more than 34,000 standards and related products, as well as online guidance documents
- Expert training online or face-to-face through our public training courses
- Regulatory updates and newsletters focusing on industry changes, helping you to plan for the future
- Webinars delivered by our experts on regulatory issues
- Comprehensive white papers providing the latest insights on key industry topics

Our website offers useful resources. You can find white papers, guidance documents and webinars.

To find out more, visit [bsigroup.com/medical](http://bsigroup.com/medical)

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CE-Excellence

BSI CE-Excellence Programs are designed to support manufacturers seeking timely and effective market access. Our services combine efficiency with the integrity, independence, and thoroughness you expect from BSI.

**CE-Standard**
The CE-Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert via phone and email, as required.

**CE-Dedicated**
The CE-Dedicated review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Product Expert, who uses the time allocated to your company to conduct a focused review of your technical documentation. This allows you to interact with your BSI product expert, providing them information during the review. The CE-Dedicated service improves the efficiency of the process, and provides predictability in your planning of the review.

For more information on our CE-Excellence services call BSI on +44 345 080 9000 or visit our CE marking webpage

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**Note:** Our services do not guarantee a CE Marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation. CE-Dedicated is not available for devices utilizing animal tissue, blood derivatives or medicinal substances.
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