## Contents

- Class Is/Im/Ir devices: 2
- Class IIa devices: 4
- Class IIb Annex VIII rule 12 devices: 8
- Class IIb implantable – Well-Established Technologies (WET): 10
- Class IIb non-implantable non rule 12 devices (non WET): 10
- Class IIb implantable devices (excluding WET): 14
- Class III non-implantable devices: 16
- Class III implantable devices: 18
- Custom-made Class III implantable devices: 20
- Custom-made devices (excluding custom-made Class III implantable devices): 22
- Class I devices (excluding Class Is/Im/Ir devices): 23

**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.
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)

CE Marking
(Annex V)
CE 0086 or 2797

+ Class Ir (Class I re-usable surgical instruments)

* Limited to sterility, metrology or re-use aspects as applicable
CLASS Is/Im/Ir DEVICES

<table>
<thead>
<tr>
<th>Class Is/Im/Ir devices</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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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Recert</td>
<td>Yes</td>
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<td>Microbiology Audits</td>
<td>Yes*</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes*</td>
<td>N/A</td>
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<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>N/A</td>
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<td>Consultations (Rule 14, Rule 18, Rule 21)</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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<td>Summary of Safety and Clinical Performance (Article 32)</td>
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*If sterile or re-usable surgical instruments

Clinical Evaluation Report updates
- Updated as per Manufacturer’s clinical evaluation plan

Post Market Clinical Follow-Up Update Report (Article 61)
- Updated as per Manufacturer’s PMS, PMCF plans; NB QMS audits to verify implementation of the plan by sampling complaints, vigilance information etc.

Periodic Safety Update Report (Article 86)
- N/A | N/A | N/A | N/A | N/A | N/A |

Unannounced Audits (BSI policy as of Feb 2019)
- At least once every 5 years
Class IIa devices

Class IIa

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 0086 or 2797
# CLASS IIa NON-IMPLANTABLE DEVICES

<table>
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<tr>
<th>Class IIa non-implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits (if sterile)</td>
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</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Sample per category of devices</td>
<td>As per the Technical Documentation Sampling Plan</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; NB to review as per Technical Documentation Sampling Plan

**Post Market Clinical Follow-Up Update Report (Article 61)**

Updated as per Manufacturer’s PMS, PMCF plans; NB to review as per Technical Documentation Sampling Plan

**Periodic Safety Update Report (Article 86)**

PSUR update required at least once every 2 years; NB to review as per Technical Documentation Sampling Plan

**Unannounced Audits (BSI policy as of Feb 2019)**

At least once every 5 years
### Class IIa devices continued

**CLASS IIa IMPLANTABLE DEVICES**

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<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
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</tr>
<tr>
<td>Technical Documentation Assessment</td>
<td>Sample per category of devices</td>
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</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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<td>N/A</td>
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<td>Yes</td>
<td>Updated at least annually “if indicated”; NB to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments</td>
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**Clinical Evaluation Report updates**

Updated as per Manufacturer’s clinical evaluation plan; NB to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments

**Post Market Clinical Follow-Up Update Report (Article 61)**

Updated at least annually; NB to review as per Technical Documentation Sampling Plan or at the time of PSUR assessments

**Periodic Safety Update Report (Article 86)**

Updated when necessary and at least every two years; submitted to NB via EUDAMED for NB review

**Unannounced Audits (BSI policy as of Feb 2019)**

At least once every 3 years
Our website offers a wealth of useful resources including white papers, guidance documents and webinars. To find out more, visit bsigroup.com/medicaldevices
Class IIb Annex VIII Rule 12 devices

- Annex IX QMS Chapters I, III
- Annex X Type Examination
- Annex IX Chapter II Technical Documentation Assessed per generic device group
- 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)
- CE Marking (Annex V) CE 0086 or 2797
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.

### CLASS IIb ANNEX VIII RULE 12 DEVICES

<table>
<thead>
<tr>
<th>Class IIb Annex VIII Rule 12 devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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<tr>
<td></td>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
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<td></td>
<td>Technical Documentation</td>
<td>Sample per Generic Device Group</td>
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<tr>
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<td>Consultation Procedure (Article 54)</td>
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**Clinical Evaluation Report Updates**

Updated as per Manufacturer’s clinical evaluation plan; NB 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; NB to review updates as per Technical Documentation Sampling Plan

**Periodic Safety Update Report (Article 86)**

Updated at least annually; NB to review updates as per Technical Documentation Sampling Plan

**Unannounced Audits (BSI policy as of Feb 2019)**

At least once every 5 years
Class IIb implantable WET
Class IIb non-implantable, non rule 12, non 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.
# CLASS IIb IMPLANTABLE WET

<table>
<thead>
<tr>
<th>Class IIb implantable WET devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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</thead>
<tbody>
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<tr>
<td>QMS Audits</td>
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<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
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<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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<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>
</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
<td>Yes</td>
<td>Updated at least annually “if indicated”; NB to review updates as per Technical Documentation Sampling Plan or at the time of PSUR assessments</td>
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**Clinical Evaluation Report updates**

Updated as per Manufacturer’s clinical evaluation plan; NB to review as per Technical Documentation Sampling Plan

**Post Market Clinical Follow-Up Update Report (Article 61)**

Updated at least annually; NB 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 NB via EUDAMED for NB review (assuming WET devices are implantable devices)

**Unannounced Audits (BSI policy as of Feb 2019)**

At least once every 3 years

Continued on page 12
## Class IIb NON-IMPLANTABLE, NON WET, NON RULE 12

<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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<tr>
<td></td>
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<td>Y1</td>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
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<td>Microbiology Audits</td>
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<td>N/A</td>
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<tr>
<td>Technical Documentation Assessment</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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</tr>
<tr>
<td>Summary of Safety and Clinical Performance (Article 32)</td>
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### Clinical Evaluation Report updates
- Updated as per Manufacturer’s clinical evaluation plan; NB 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; NB to review updates as per Technical Documentation Sampling Plan

### Periodic Safety Update Report (Article 86)
- Updated at least annually; NB to review updates as per Technical Documentation Sampling Plan

### Unannounced Audits (BSI policy as of Feb 2019)
- At least once every 5 years
BSI CE-Excellence Programmes are designed for medical device manufacturers wanting to get their products to European markets efficiently and safely.

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 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.

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.

For more information on our CE-Excellence services call BSI on +44 345 080 9000 or visit bsigroup.com/ce-excellence
Class IIb implantable devices (excluding WET)

Class IIb implantable devices (non-WET)

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 0086 or 2797
### Class IIb Implantable Non-WET Devices

<table>
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<tr>
<th>Class IIb implantable non-WET devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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<tbody>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Microbiology Audits</td>
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<td>N/A</td>
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<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
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<tr>
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<td>Yes</td>
<td>Updated at least annually “if indicated”; NB 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; NB 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; NB to review at the time of PSUR reviews or substantial change reviews

**Periodic Safety Update Report (Article 86)**
- Updated at least annually; submitted to NB via EUDAMED for NB review

**Unannounced Audits (BSI policy as of Feb 2019)**
- At least once every 3 years
Class III non-implantable devices

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

*Consultation

Declaration of conformity (Annex IV)

CE Marking (Annex V)
CE 0086 or 2797
## CLASS III NON-IMPLANTABLE DEVICES

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<tr>
<th>Class III non-implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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</thead>
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<td>QMS Audits</td>
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<tr>
<td>Microbiology Audits</td>
<td>Yes (if sterile)</td>
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<td>Technical Documentation Assessment</td>
<td>Review for every device</td>
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<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>N/A N/A N/A N/A</td>
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<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>
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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”; NB 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; NB 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; NB to review at the time of PSUR reviews or substantial change reviews

### Periodic Safety Update Report (Article 86)
- Updated at least annually; submitted to NB via EUDAMED for NB review

### Unannounced Audits (BSI policy as of Feb 2019)
- At least once every 3 years
Class III Implantable devices

(including devices with medicinal substances, human tissue or animal tissue derivatives with TSE risk, Class III Rule 21 devices.)
**CLASS III IMPLANTABLE DEVICES**

<table>
<thead>
<tr>
<th>Class III implantable devices</th>
<th>Initial Conformity Assessment</th>
<th>SURVEILLANCE</th>
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<tr>
<td>QMS Audits</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Microbiology Audits (if sterile)</td>
<td>N/A</td>
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<td>Technical Documentation Assessment</td>
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<tr>
<td>Clinical Evaluation Consultation Procedure (Article 54)</td>
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<td>May be required if any modifications to the device adversely affect the risk-benefit ratio</td>
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<tr>
<td>Consultations (Rule 14, Rule 18, Rule 21)</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>
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<td>Updated at least annually &quot;if indicated&quot;; NB 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; NB 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; NB review at the time of PSUR reviews or substantial change reviews

**Periodic Safety Update Report (Article 86)**

Updated at least annually; submitted to NB via EUDAMED for NB review

**Unannounced Audits (BSI policy as of Feb 2019)**

At least once every 3 years
Custom-made Class III implantable devices

Annex IX QMS
Chapter I

Annex XI – Part A
Production Quality Assurance

Statement
Annex XIII Section 1

CE Certificate issued CE 0086 or 2797
## Custom-made Class III Implantable Devices

<table>
<thead>
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<th>Custom-made Class III implantable devices</th>
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<td>Microbiology Audits</td>
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### Clinical Evaluation Report Updates

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<tr>
<td><strong>Post Market Clinical Follow-Up Update Report</strong> (Article 61)</td>
<td><strong>As per Manufacturer’s PMS, PMCF plans; NB QMS audits to verify implementation of the plan</strong></td>
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<td><strong>Periodic Safety Update Report</strong> (Article 86)</td>
<td><strong>Updated at least annually; unclear whether to be submitted to EUDAMED for NB review or not; NB to verify updates at the time of surveillance QMS audits</strong></td>
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<td><strong>Unannounced Audits</strong> (BSI policy as of Feb 2019)</td>
<td><strong>At least once every 3 years</strong></td>
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<td></td>
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</table>
Custom-made devices
(excluding custom-made Class III implantable devices)

Note: No Notified Body involvement

- **Custom-made (excl Class III implantable custom-made devices)**
- **Annex XIII Documentation**
- **Collect PMS, PMCF data** as per Part B of Annex XIV
- **Statement** Annex XIII Section 1
Class I devices
(excluding Class Is/Im/Ir devices)

Note: No Notified Body involvement

Class I

Annex II and III
Technical Documentation

Declaration of conformity (Annex IV)

CE Marking (Annex V) CE

Note: No Notified Body involvement
Your resource for excellence

Talk to BSI

- We have 4,600 colleagues globally
- Offices in 31 countries around the world
- Over 84,000 clients operating in 193 countries
- Together our clients account for 75% of the FTSE 100, 49% of the Fortune 500 and 77% of the Nikkei 225 listed companies
- Over 600 colleagues within medical devices.

Additional services

Medical device newsletter service
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Comprehensive white papers
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