QMS Aspects of the MDR (& IVDR)

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Global QMS Manager Medical Devices
27 February 2018
This Presentation

1. The clock is ticking!
2. Dates & priorities
3. BSI Assessments
4. QMS Items for MDR / IVDR
   - Immediate checks / post market
   - For full MDR / IVDR Application
5. MDD to MDR Certification
6. Next Steps...

bsi.
The Clock is Ticking!

- What products currently on the EU market?
- What products on the market post 2024?
- What needs certification in 2022 / 2024?
- What is ‘in’ the MDR / IVDR that wasn’t previously? i.e. Will need CE Certification sooner?
- What is reclassified?
- What are the priority products?
MDR Transition (Article 120)

Entry into Force (OJEC + 20 days) (25 May 2017)

05 May 2017 Adoption of MDR

Transition period 3 years

Date of Application (26 May 2020)

MDD/AIMD certificate validity (4 years)

Annex IV certificates expire (27 May 2022)

Last MDD/AIMD certificates expire (27 May 2024)

27 May 2025 No more « placing on the market » of devices covered by MDD/AIMD certificates

MDD/AIMD certificates (max 5-year expiry from issue/renewal date)

NBs designation under MDR

Last MDD/AIMD certificates expire (27 May 2024)

No more « placing on the market » of devices covered by MDD/AIMD certificates

27 May 2025

MDD/AIMD certificates

26 May 2020

Date of Application

25 May 2017

Entry into Force (OJEC + 20 days)

05 May 2017

Adoption of MDR
MDR Transition (Article 120)

Entry in to Force 25 May 2017

Adoption of MDR 05 May 2017

Date of Application 26 May 2020

Transition period 3 years

MDR/AIMDD certificate validity (4 years)

25 May 2017

MDD/AIMDD certificates can be issued/re-issued/renewed

MDD/AIMDD Annex IV ... devices with changes made to Design or Intended Purpose require MDR Certification after 26 May 2020

NBs can apply for designation 26 Nov 2017

MDR certificates

27 May 2025

No more « making available or putting into service » of devices covered by MDD/AIMDD certificates

All require MDR Certification from 26 May 2020

27 May 2024

MDD/AIMDD certificates void on 27 May 2022

27 May 2025

NBs designation under MDR

- Class I reusable
- Class III custom made implantable
- Reclassified Software (previously Class I)
- Devices with no medical purpose (once CS available)

• Class I reusable
• Class III custom made implantable
• Reclassified Software (previously Class I)
• Devices with no medical purpose (once CS available)
However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.
MDR Transition (Article 120)

- Adoption of MDR: 05 May 2017
- Entry into Force: 25 May 2017
- Transition period: 3 years
- MDD/AIMDD certificates can be issued/re-issued/renewed
- NBs can apply for designation: 26 Nov 2017
- Date of Application: 26 May 2020
- MDD/AIMDD certificate validity: (4 years)
- MDD/AIMDD Annex IV certificates void on 27 May 2022
- MDD/AIMDD certificates void: 27 May 2024
- No more « making available or putting into service » of devices covered by MDD/AIMDD certificates: 27 May 2025
- NBs designation under MDR

- Post market surveillance
- Market surveillance
- Vigilance
- Registration of economic operators and devices
IVDD certificate validity (2 years)

IVDR Transition (Article 110)

Entry into Force 25 May 2017

Adoption of IVDR 05 May 2017

Date of Application 26 May 2022

IVDD certificates can be issued/re-issued/renewed

Transition period 5 years

IVDD certificate validity (2 years)

27 May 2024

IVDD certificates void

27 May 2025

No more « making available or putting into service » of devices covered by IVDD certificates

NBs can apply for designation 26 Nov 2017

NBs designation under MDR

IVDR certificates

8
BSI Assessments
BSI QMS AUDIT

ISO 13485
MDD AIMD IVDD
ISO 9001

Assessment Requirements

Now

Assessment Requirements
Future

Assessment Requirements

BSI QMS AUDIT

ISO 13485

ISO 9001

MDSAP

MDR / IVDR

‘Post market’ aspects
MDR – 26 May 2020
IVDR – 26 May 2022
BSI QMS Audits

- What is the procedure?
- Show me the process
- What is the defined and documented system for...
- Do you have evidence of?
BSI Audits for MDR Certification

- Microbiology & Sterilisation Audits
- Unannounced Audits (ongoing per MDD / MDR)
- Quality System Audits
- Technical Documentation Reviews

- No changes as a result of MDR / IVDR
- New frequencies already applied
- Once per 3 years for Class III & Implants
- Once per 5 years for rest
IVDR Pilot Audits - Volunteers Required!

Pilot IVDR QMS Audits

- Not a full formal audit, could be:
  - Sections of site / systems
  - Section of QMS
  - One product range
  - Several sub-systems

- No non-conformities (observations)
- Assessment will not count (i.e. full formal QMS assessment required at later date)
- Audit of process / systems and evidence as far as is reasonable / possible
- BSI accept full implementation will not be possible in all cases (e.g. SRN, UDI, EUDAMED etc)

BSI Draft MDR / IVDR Processes and Procedures:

- DRAFT MDR / IVDR Assessment Procedures
- DRAFT MDR and IVDR Checklist (Approx. 100 items dependant on Devices, Conformity Assessment Route etc)
QMS Items for MDR / IVDR
- Immediate checks / post market
IVDR
26 May 2022
BSI QMS Audits from 26 May 2020 / 2022
For All **EXISTING** CE Certifications – 3 Main Areas

1) Registrations
   - Devices (Article 29)
   - Economic Operators (Article 30)
   - Manufacturers, authorised representatives and importers (Article 31)

2) Post Marketing Surveillance Systems
   - For Plan (Article 84) & Report (Article 85 – Class I)
   - Vigilance Reporting requirements - Systems for Serious Incident, FSCA and Trend Reports (Article 87 & 88)
   - PSUR (Article 86 – Class IIa, IIb, III) – post MDR certification

3) Market Surveillance (Article 93)
   - Provision / access to information, devices, sites by Competent Authorities
Economic Operators

Article 2 Definitions

• A manufacturer
• An authorised representative
• An importer
• A distributor
• Or the person referred to in Article 22(1) and 22(3)
  i.e. Provider of Procedure Packs or Parts & Components
Economic Operators

- Manufacturer – Article 10
- Authorised Representative – Article 11 & 12
- Importer – Article 13
- Distributor – Article 14
- Procedure packs or parts / components – Article 22 & 23
- Translation / Re-packaging / Re-labelling – Article 16*

*Need EC Certificate

Major increase in responsibilities for ALL
Registration of Devices & Economic Operators

- Devices (Article 29)
- Economic Operators (Article 30)
- Manufacturers, authorised representatives and importers (Article 31)
### QMS processes and Economic Operators

<table>
<thead>
<tr>
<th></th>
<th>Manufacturer (Article 10)</th>
<th>Authorised representative (Articles 11 and 12)</th>
<th>Importer (Article 13)</th>
<th>Distributor (Article 14)</th>
<th>Assembler (Article 22)</th>
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<tbody>
<tr>
<td>Eudamed registration</td>
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<td>Technical documentation</td>
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<tr>
<td>Design and development, Manufacture or assembly</td>
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<tr>
<td>Handling, storage and distribution</td>
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<td>Nonconformities</td>
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<td>FSCA</td>
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<td>UDI/Labelling</td>
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<td>Complaints</td>
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<td>PMS</td>
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<tr>
<td>Person responsible for RC</td>
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</table>
Vigilance
Requirements for Reporting Serious Incidents & FSCAs – Article 87

New regulation wording on ‘Causal’ relationship between device and incident

<table>
<thead>
<tr>
<th>Type of incident</th>
<th>Directives</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Public Health Threat</td>
<td>2 days</td>
<td>2 days</td>
</tr>
<tr>
<td>Death or Unanticipated Serious Deterioration in the State of Health</td>
<td>10 days</td>
<td>10 days</td>
</tr>
<tr>
<td>Others</td>
<td>30 days</td>
<td>15 days</td>
</tr>
</tbody>
</table>

- Systems
- Process
- Procedures
- Evidence
Any negative trends vs Risk Management Documentation

any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis ... and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.
QMS Items for MDR / IVDR

– Following application for certification
Initial MDR or IVDR Assessment

- For Brand New Initial Applications – Normal Initial Assessment Durations Apply
- For Manufacturers ‘Transitioning’ from MDD / AIMD to MDR likely 1 – 4 days Initial Assessment (in addition to current MDD durations)
Article 10/10 – Manufacturers

Clause 9 – The quality management system shall address at least the following aspects:

a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;

b) identification of applicable safety and performance requirements and exploration of options to address these requirements;

c) responsibility of the management;

d) resource management, including selection and control of suppliers and sub-contractors;

e) risk management;

f) clinical / performance evaluation, including PMCF / PMPF;

g) product realisation, including planning, design, development, production and service provision;

Much already covered in ISO 13485:2016
Clause 9 – The quality management system shall address at least the following aspects:

- **verification of UDI assignments**, ensuring consistency of information provided;
- setting-up, implementation and maintenance of a PMS system;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
- processes for reporting of serious incidents and FSCA in the context of vigilance;
- management of corrective and preventive actions and verification of effectiveness;
- processes for monitoring and measurement of output, data analysis and product improvement.

**ISO 13485:2016**

- 7.5.8
- 8.2.1, 8.5.1
- 7.2.3, 8.2.3
- 8.2.2, 8.2.3
- 8.5.2, 8.5.3
- 8
Initial Assessment to MDR / IVDR

... Some key areas we will be covering in BSI QMS Audits

- General QMS Requirements
  - Continual Improvement
  - Strategy for Regulatory Compliance

- Person Responsible for Regulatory Compliance

- UDI (+ Implant Card)

- Clinical processes – evaluation and investigation

- Post Market Processes – PMS Systems, PSUR, SSCP

- Technical Documentation Processes and Procedures
Person Responsible for Regulatory Compliance
Article 15

- Required for both Manufacturers and Authorised Representatives
- Must have expertise in medical devices, including degree and four years’ professional experience
- Responsible for ensuring:
  - Product conformity checked via appropriate QA release
  - Technical documentation and DoC maintained
  - PMS & reporting obligations are met
  - Investigational devices: statement of safety and compliance with SPRs
- Note the concessions for small or micro enterprises with respect to requirements
UDI – Article 27 (24)

• On the label (not shipping containers)
• On vigilance reports … the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87.
• EU declaration of conformity - the Basic UDI device identifier ('Basic UDI-DI’ as defined in Annex V Part C) of the device shall appear on the Doc referred to in Article 19.
• Technical documentation - Annex II
• Implant Card – Article 18
• Notified Body CE Certificate – Annex XII
# UDI Dates

<table>
<thead>
<tr>
<th>GS1, HIBCC and ICCBBA designated UDI issuing entities (Article 123,3i; Article 113,3h)</th>
<th>May 26, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDI carrier on the label and higher levels of packaging (Article 123,3f; Article 113,3e)</td>
<td>May 26, 2021 - Implantable devices and Class III devices; May 26, 2023 - Class IIa and IIb (non-implantable) devices and Class D devices; May 26, 2025 - Class I devices, Class B and Class C devices; May 26, 2027 - Class A devices</td>
</tr>
<tr>
<td>UDI carrier on reusable devices (Article 123,3g)</td>
<td>May 26, 2023 - Reusable Class III devices; May 26, 2025 - Reusable Class IIa and reusable IIb (non-implantable) devices; May 26, 2027 - Reusable Class I devices.</td>
</tr>
</tbody>
</table>
The manufacturer of an implantable device (not sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors), shall provide together with the device the following:

- device name, serial number, lot number
- Unique Device Identification, device model
- manufacturer name, address and website

- any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- any information about the expected lifetime of the device and any necessary follow-up;
- any other information to assure a safe use of the device by the patient
- including the information in Annex I, Section 23.4 (u) – qualitative and quantitative information on the materials and substances to which patients can be exposed

Available to patient on implant card
Throughout the lifetime of the device concerned the PSUR shall set out:

- Conclusions of the benefit-risk determination
- Main findings of PMCF
- Volume of Sales
- Estimate of the size and other characteristics of the Population that use the device
- Where practicable usage frequency of the device

BSI QMS Audit Check of Systems, Procedures etc – Detail in Technical Documentation Reviews

Periodic Safety Update Report - Article 86

Manufacturers of class IIa, class IIb and class III devices shall prepare a periodic safety update report (‘PSUR’) for each device and where relevant for each category or group of devices

Manufacturers of class IIb and III devices shall update the report at least annually

Class IIa devices shall update the report when necessary and at least every two years

For class III or implantable devices shall submit PSUR reports by means of the electronic system to the notified body

Notified Body shall review, add its evaluation with details of any action taken, and make available to the Competent Authorities through the electronic system
Summary of Safety & Clinical Performance - MDR Article 32

SSCP shall include at least the following:

• Manufacturer + SRN
• Device + UDI-DI
• Intended Purpose, Indications, Contra-indications and Target Population
• Description, previous variant(s), differences, accessories, other products intended to be used in combination
• Possible diagnostic or therapeutic alternatives
• Harmonised Standards / Common Specifications
• Summary of the Clinical Evaluation Report + PMCF
• Suggested profile and training for users
• Information on residual risks, undesirable effects, warnings & precautions

For implantable devices and for class III devices, the manufacturer shall draw up a summary of safety and clinical performance.

The SSCP shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be made available to the public via EUDAMED.

Article 61 – Clinical Evaluation

For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance (referred to in Article 32) shall be updated at least annually with such data.
### Summary Safety & Clinical Performance SSCP - Article 32 Periodic Safety Update Report PSUR - Article 86

<table>
<thead>
<tr>
<th>Class</th>
<th>PSUR</th>
<th>SSCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Strictly N/A however Article 85 – Class I PMS Report updated ‘when necessary’</td>
<td>-</td>
</tr>
<tr>
<td>Class Is / Im / Ir</td>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Class IIa</td>
<td>As necessary and at least every 2 Years</td>
<td>-</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Annual</td>
<td>-</td>
</tr>
<tr>
<td>Class IIb Implantable</td>
<td>Annual to NB (via EUDAMED)</td>
<td>Annual to NB (to EUDAMED)</td>
</tr>
<tr>
<td>Class III</td>
<td>Annual to NB (via EUDAMED)</td>
<td>Annual to NB (to EUDAMED)</td>
</tr>
</tbody>
</table>
Annex IX Chapter I – 3.3 + 3.5

Class IIa, IIb, III

... At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly.

For class III devices surveillance assessment shall include a test of the approved parts and/or materials that are essential for the integrity of the device, including, where appropriate, a check that the quantities of produced or purchased parts and/or materials correspond to the quantities of finished devices.
Witness Testing & Reconciliation

- New / strengthened requirement to perform or request tests to verify proper functioning of the QMS
- Currently routine in Unannounced Audits
- BSI Policy to witness where possible
- Focus on inprocess and / or final product inspection
- Reconciliation of materials for class III
Safety & Performance Requirements

1. Safe, Perform as Intended, State of the Art
2. Risk reduction as far as possible
3. Risk Management
4. Risk Control
5. Risk of Use Error
6. Lifetime
7. Packaging, Transport, Storage
8. Undesirable side-effects minimised & Risks<Benefits
9. Annex XVI “no risk at all” or “no more than the maximum acceptable risk”
10. Chemical, Physical & Biological Properties
11. Infection & Microbial Contamination
12. Devices incorporating a medicinal product and devices composed of substances that are absorbed by or locally dispersed in the human body
13. Devices incorporating materials of biological origin
14. Construction and interaction with the environment
15. Devices with a diagnostic or measuring function
16. Protection against radiation
17. Electronic programmable systems
18. Active devices and devices connected to them
19. Requirements for AIMD
20. Protection against mechanical and thermal risks
21. Protection against the risks posed to the patient or user by supplied energy or substances
22. Protection against the risks posed by medical devices intended for use by lay persons
23. Information Supplied
Summary of Key Changes Impacting QMS Processes

**Systems / Process**
- Strategy for Regulatory Compliance
- Implementing & Delegating Acts
- Harmonised Standards, Common Specifications
- Clinical Evaluation & Investigation Processes
- Person Responsible for Regulatory Compliance
- Registration of Economic Operators and Devices
- Communication with Regulators & Stakeholders

**Classification VS Conformity Assessment Route**
- Procedures for Clinical Evaluation
- Procedures for Technical Documentation
- SPR Checklist / Evidence
- Labelling, UDI
- Management of Changes

**Technical Documentation**
- DRAFT DoC
- SSCP & PSUR

**Device Specific**
- No medical purpose
- Custom made (Class III)
- Nanoparticles
- Non-viable Animal or Human Tissues
- Software
- System & procedure packs
- Medicinal Substances
- Parts / Components
Route from MDD to MDR Certification
Manufacturers Route from MDD to MDR Certification

- QMS MDR Audit
- MDR Technical Documentation review
- MDR Microbiology & Sterilisation Review*

*Where applicable

Recommendation(s) for MDR Certification
MDD to MDR Certification – QMS Certificates

- MDR QMS Certificate (Annex IX Chapter I or Annex XI Part A) must be issued first (or concurrently with a corresponding product certificate)

- MDR QMS Certificate first issue will include in scope only devices / ranges with:
  ✓ Successfully completed MDR QMS Audit AND
  ✓ Successfully completed MDR Technical Documentation Review
MDD to MDR Certification – Product Certificates

- For devices requiring product certificates will require concurrent certificate issue / reissue once
  
  ✓ Successfully completed MDR QMS Audit AND
  
  ✓ Successfully completed MDR Technical Documentation Reviews

=> Certificate decision process for review for issue of
- Annex IX Chapter I QMS certificate
- Annex IX Chapter II Product certificate
MDD to MDR Certification – Larger Manufacturers & Scopes

- For larger manufacturers / scopes - as further Technical Documentation reviews completed and Product Certificates ready to be issued, the MDR QMS Certificate can be re-issued to ‘add-in’ additional devices or range

- Where possible, aim is to conduct one initial QMS MDR certification audit / recommendation (i.e. not multiple MDR initial QMS visits to same manufacture).

- MDR activity and compliance will be verified annually as part of normal QMS surveillance
Concurrent MDD & MDR Certificates

- Devices must be within respective certificate scopes
- Must be clear and traceable what product / batch has been produced under what system
- Look out for upcoming BSI communications on deadlines for applications for early renewals of MDD / AIMD / IVDD certificates
Next Steps
MDR Assessment Type by Device Classification

Regulatory Requirements

Class III Implants + IIb Rule 12
- QMS
- Microbiology
- Unannounced
- Technical Documentation
- + Medicinal, Animal, Human Consultation
- Clinical
- + Clinical Evaluation Consultation

Class IIb Implants
- QMS
- Microbiology
- Unannounced
- Technical Documentation
- + Medicinal, Animal, Human Consultation
- Clinical

Class IIb
- QMS
- Microbiology
- Unannounced
- Technical Documentation
- Clinical

Class Ia
- QMS
- Microbiology, Metrology, Reuse
- Unannounced

Class I
- QMS
- Unannounced

Device Classification

Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors

MDR Assessment Type by Device Classification

Device Classification
Approaching the MDR & IVDR

- Information!

- MDR/IVDR
  - Products - Now vs Future
  - Plan & Process to Prepare
  - Implement
  - Roll-Out & Verification
  - NB Audit - Review & Amend

- QMS
  - Plan
  - Do
  - Check
  - Act
Resources

bsigroup.com/MDR-Revision

bsigroup.com/IVDR-Revision

bsigroup.com/iso13485revision

MDR and IVDR Critical Update:

BSI has submitted designation applications for the Medical Devices Regulation (Regulation (EU) 2017/745) and the In Vitro Diagnostic Regulation (Regulation (EU) 2017/746) to both the UK and the Netherlands Competent Authorities. On 26 November 2017 was the first day that Notified Bodies were allowed to apply for designation under the MDR and IVDR. BSI were among the first wave of Notified Bodies to submit for both Regulations. The next step is for the Designating Authority, MHRA in the UK and RGD in The Netherlands, to review our application and write a preliminary report to be sent to the Commission so that they can schedule Joint Assessment audits of BSI.

BSI is proud to work towards designation for these critical Regulations and will continue to strive for excellence in our Notified Body activities over the transition period. We will ensure that you are kept up to date with the progression going forward.

New Medical Devices Regulation now published