TIC Council Webinar
TIC Sector and the Cybersecurity of Medical Devices in Europe
23 July 2020
TIC Council

The Independent Voice of Trust

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- ~90-member companies & organizations active in more than 160 countries (HQ mapped)
- TIC Council has its head office in Brussels. It also has an office in Washington and
TIC Council Mission

As the voice of the global independent testing, inspection and certification industry, the TIC Council engages governments and key stakeholders to advocate for effective solutions that protect the public, support innovation and facilitate trade.

The TIC Council works with its members to promote best practices in safety, quality, health, ethics and sustainability.
Webinar

TIC SECTOR AND THE CYBERSECURITY OF MEDICAL DEVICES IN EUROPE

23 July 2020  15:00

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Commission update
TIC Council webinar – Cybersecurity of medical devices

Directorate-General for Health and Food Safety (DG SANTE)
Anna-Eva AMPelas – Head of Unit B.6 on Medical Devices and Health Technology Assessment
Agenda

1. COVID-19 and MDR/IVDR Implementation
2. Impacts of the new Regulations (MDR/IVDR) on cybersecurity of medical devices and regulators’ expectations
3. How should manufacturers consider interface between MDR/IVDR and other regulations (such as the GDPR)?
1) COVID-19 and MDR/IVDR implementation
1) COVID-19 and MDR/IVDR implementation

- MDR postponement of application date
- Ramping up of production
- European Standards made freely available
- Numerous COVID-19 related guidance published
- Combatting export restrictions
- Derogations
- Joint procurement Agreement
- Clearing House
Regulation (EU) 202/561 and main consequences

- Regulation (EU) 2020/561 adopted on 23 April 2020 amending MDR, as regards the **dates of application** of certain of its provisions

- Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of **designations** and the **surveillance and monitoring of** notified bodies

- Commission Recommendation (EU) 2020/403 of 13 March 2020 on **conformity assessment and market surveillance** procedures within the context of the COVID-19 threat
MDCG guidance and other COM documents published COVID-19 (I)

- **MDCG Guidance** on temporary extraordinary measures related to medical device **notified body audits** during COVID-19 quarantine orders and travel restrictions
- **MDCG Guidance** on the renewal of designation and monitoring of **notified bodies** under Directives 90/385/EEC and 93/42/EEC to be performed in accordance with Commission Implementing Regulation (EU) 2020/666 amending Commission Implementing Regulation (EU) 920/2013
- **Guidance** on how to check if medical devices and PPE can be **lawfully placed on the EU market** and thus purchased and used
- **Commission guidelines** on the adoption of **Union-wide derogations** for medical devices
MDCG guidance and other COM documents published COVID-19 (II)

- **MDCG Guidance** on regulatory requirements for **ventilators** and related accessories
- **Communication from the Commission** concerning Guidelines on COVID-19 **in vitro diagnostic tests** and their performance
- **Working document of Commission services** on **performance of COVID-19 test methods** and devices and proposed performance criteria
- **Database** of devices and publicly available **performance data COVID-19 In Vitro Diagnostic Devices and Test Methods**
- **Guidance** on Medical devices, Active implantable medical devices and in vitro diagnostic medical devices **in the COVID-19 context**
MDCG guidance and other COM documents published COVID-19 (III)

- **Guidance** to increase production of safe medical supplies (PPE, hand gel, 3D printing)
- **Guidance** on face masks
- **IMDRF Standards Checklist** modified in scope of COVID-19
- **Q&A** on conformity assessment procedures for protective equipment
- **New lists** of harmonised standards made available for medical devices
- **European standards** for medical supplies made freely available to facilitate increase of production
- **Standardisation request** in support of the new Regulations on medical devices
- **Commission recommendation** on conformity assessment and market surveillance procedures
MDR/IVDR Implementation – Published Guidance

March 2020
✓ Update of guidance on implant card
✓ Transitional provisions of article 120 (3) and (4) for class I medical device
✓ Significant changes regarding transitional provisions in Art.120
✓ Clinical evaluation/ Performance evaluation of medical device software

April 2020
✓ Update of guidance on Article 54(2)b
✓ PMCF templates
✓ Sufficient clinical evidence for legacy devices
✓ Clinical evaluation – Equivalence

May 2020
✓ Safety reporting in clinical investigations

June 2020
✓ Consultations of authorities on devices with ancillary substances and TSE susceptible tissues
✓ Update of guidance on UDI for systems and procedure packs

July 2020
✓ Clinical evaluation assessment report template
MDR/IVDR Implementation

Expert panels

• Rolling Plan 3 June 2020

Implementing Acts: for information

More than 80 empowerments for implementing and delegated acts (including Common Technical Specifications – CS)(of which 18 mandatory)

Next in line for MD:
  o Common specifications on reprocessing of single-use devices (Q3 2020)
  o Common specifications of devices without medical purpose (Q4 2020)
  o EUDAMED impl. Act (Q4 2020)
MDR/IVDR Implementation

Implementing Acts: for information: Standardisation supporting the new Regulations

- Standardisation Request (Commission Implementing Decision with Annexes) according to Art. 10 of the Standardisation Regulation (EU) 1025/2012
- Committee on Standards (Member States representatives) expressed a positive opinion
- Commission adopted an Implementing Decision on 15 May 2020 and notified it to CEN and CENELEC.
- CEN and CENELEC rejected the Request on 16 June 2020 which can result in a lack of legal basis for the standardisation work in support of MDR and IVDR and for the publication of references to standards in the OJEU under MDR/IVDR. Could lead to increased use of Common specifications.
**IVDR Specific**

**Current main items**

- Setting up of reference laboratories (Q3 2020/Q1 2021) – can be designated after 25 November 2020
  - Implementing act on tasks and criteria
  - Implementing act on fees
  - Call for application
- Transposing Common Technical Specifications into Common specifications for IVD Class D (Q3 2020)
- Developing new Common Specifications
- Guidance on classification – finalisation imminent
2) Impacts of the new Regulations (MDR/IVDR) on cybersecurity of medical devices and regulators’ expectations
2) Impacts of the new Regulations (MDR/IVDR) on cybersecurity of medical devices

- New regulations bring about an increased expectations for all types of medical devices including those incorporating software, as well as independent Medical Device Software (MDSW)
- New classification rules specific to software
- Increased PMS and Vigilance
- Risk Management
- Re-inforcement of the ‘lifecycle’ approach to devices
- ...
General Safety and Performance Requirements (GSPR): Annex I - cybersecurity of medical devices

- Specification of Cybersecurity Requirements included in Annex 1 of the MDR
- IT Security
- Information Security
- Operations Security
- Safety, Security and Effectiveness
- State of the Art
- Safe Design and Manufacture
- Risk Control Measures
- Verification and validation
- Risk-benefit analysis: assessing the acceptability of risk
- Documentation
- Information & labelling
2) Impacts of the new Regulations (MDR/IVDR) on cybersecurity of medical devices – cont.

- MDCG guidance specific to software

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<td>Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software</td>
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<td>MDCG 2019-16</td>
<td>Guidance on cybersecurity for medical devices</td>
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Guidance on cybersecurity for medical devices – MDCG 2019-16

General safety and performance requirements with focus on cybersecurity

- IT Security (sec. 17.4, 23.4ab)
- Operation Security (sec. 14.1, 14.2, 17.1)
- Information Security (sec. 17.2)

Basic Cybersecurity Concepts

- Safety/security and effectiveness (sec. 1)
  Reduce risk to ensure intended device performance and high level of protection of health (sec. 2, 5, 6, 9)
  - In all operation mode
  - Intended/reasonable foreseeable risk

Secure Design and Manufacture (sec. 4a)
- Risk management across the life cycle (sec. 3, 14.4, 14.5, 19.3)
- Protection against risk during intended use and reasonable foreseeable misuse (sec. 3c, 8)
- Protection against unauthorised access (sec. 17.4, 18.8)
- Identify threats, vulnerabilities, hazards, risks (sec. 3b)
- Establish risk control measures (sec. 4)
- Minimum IT security requirements (sec. 17.4, 14.5)

MDR Annex I

- Information for users, instructions and labelling (sec. 4, 23.1, 22.1, 23.4)

- Verification/validation (sec. 17.2)

- State of the art (sec. 1, 4, 17.2)

- Acceptable residual risk (sec. 4)

- Documentation* (sec. 3)

* See also Annex II of MDR
### Guidance on cybersecurity for medical devices – MDCG 2019-16

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Guidance on cybersecurity for medical devices – MDCG 2019-16 – a lifecycle approach

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<td>Update Technical Documentation (Annex II and III)</td>
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<td>Inform the Electronic System On Vigilance (Article 92)</td>
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Guidance on cybersecurity for medical devices – MDCG 2019-16

• **IT Security, Information Security, Operation Security**
Annex I of the Medical Devices Regulations explicitly sets out the requirement for manufacturers of in vitro diagnostic medical device and medical device to fulfil minimum requirements concerning hardware, IT networks3 characteristics and IT security measures, including protection against unauthorised access. All these requirements are necessary in order to run the software as intended

• **Safety, Security and Effectiveness**
Information security and IT security are addressed explicitly in Annex I 17.2 (MDR), 17.4 (MDR), 18.8 (MDR), 16.2 (IVDR) and 16.4 (IVDR) whereas "Safety and Effectiveness" issues are addressed in section 1 of Medical Devices Regulations Annex I
Guidance on cybersecurity for medical devices – MDCG 2019-16

• **Intended use and intended operational environment of use**
Manufacturers determine design inputs to ensure safety and effectiveness of products against cybersecurity risks and threats. This should be considered in accordance with the nature of the device, including the device type and intended communication technologies usage. A medical device should be designed in a layered defence in depth approach and therefore should not rely on security controls in the operating environment.

• **Reasonably foreseeable misuse**
Medical device manufacturers should ensure that a medical device is designed and manufactured in a way that ensures that the risks associated with reasonably foreseeable environmental conditions are removed or minimised. This may include the infield monitoring of the software’s vulnerabilities and the possibility to perform a device update through, for example delivering patches. During the risk management process, the manufacturer should foresee or evaluate the potential exploitation of those vulnerabilities that may be a result of reasonably foreseeable misuse.
Guidance on cybersecurity for medical devices – MDCG 2019-16

• Joint Responsibility - Specific expectations from other stakeholders
While the MDR and the IVDR provide legal obligations only with regard to manufacturers, however it should be noted that for the provision of secured healthcare services, it is important to recognise the roles and expectations of all stakeholders, such as manufacturers, suppliers, healthcare providers, patients, integrators, operators and regulators. All of these actors share responsibilities for ensuring a secured environment for the benefit of patients’ safety.

• Secure Design and Manufacture – Secure by design and lifecycle aspects
Safety, security and effectiveness are critical aspects in the design of security mechanisms of medical devices. Therefore, there is a clear requirement that these aspects need to be considered by the manufacturers from an early stage of development and manufacturing process and throughout the entire life cycle.
Guidance on cybersecurity for medical devices – MDCG 2019-16

• Lifecycle Aspects
Addressing cybersecurity risks at the design stage can help mitigate cybersecurity risks that could contribute to a breach in the confidentiality, a compromise in the integrity and availability of the medical device and its data, or intentional unauthorised access to the medical device and/or the network.

During the lifetime of the device, the manufacturer should put in place a process to gather post-market information with respect to the security of the device. This process should take into account:

1. Security incidents directly related to medical device software
2. Security Vulnerabilities that are related to the medical device hardware/software and the 3rd party hardware/software used with the medical device.
3. Changes in the threat landscape, including interoperability aspects

The manufacturer should evaluate the information thus gathered, evaluate the associated security and safety risk and take appropriate measures that control the risk associated with such security incidents or vulnerabilities.
Guidance on cybersecurity for medical devices – MDCG 2019-16

• **Post-Market Surveillance of a medical device’s life cycle**
  a crucial aspect that manufacturers shall implement as cybersecurity vulnerabilities change and evolve over time and controls implemented during pre-market activities may be inadequate to maintain an acceptable benefit-risk level. An effective and successful post-market cybersecurity surveillance program should include the following aspects:
  - operation of the device in the intended environment
  - sharing and dissemination of cybersecurity information and knowledge of cybersecurity vulnerabilities and threats across multiple sectors
  - vulnerability remediation
  - incident response

• **Vigilance**
  The manufacturer is responsible for reporting all serious incidents and field safety corrective actions (FSCA). The manufacturers will need to carry out investigations of serious incidents related to a cybersecurity in order to provide a comprehensive description of the serious incident and involve the distributors of the device and, where applicable, the authorised representative and importers in the system, in order to obtain the information needed from the market, especially for FSCA or issued field safety notices (FSN) so that to ensure required actions are followed and completed in a timely manner.
3) How should manufacturers consider interface between MDR/IVDR and other regulations?
Cross cutting legislation

• At EU level, the following legislative acts are relevant to the cybersecurity of medical devices or to operators dealing with protecting or processing of personal data stored in medical devices and might apply in parallel to the Medical Devices Regulations:

- Network and Information Systems Directive (NIS)*
- General Data Protection Regulation (GDPR)*
- EU Cybersecurity Act
Network and Information Systems Directive (NIS)


• Provides legal measures to boost the overall level of cybersecurity in the EU by ensuring:
  o Member States preparedness by requiring them to be appropriately equipped,
  o Cooperation among all the Member States, by setting up a cooperation group, in order to support and facilitate strategic cooperation and the exchange of information among Member States.
  o A culture of security across sectors which are vital for our economy and society and moreover rely heavily on ICT, such as energy, transport, water, banking, financial market infrastructures, healthcare and digital infrastructure. Businesses in these sectors that are identified by the Member States as operators of essential services will have to take appropriate security measures and to notify incidents of significant impact to the relevant national authority.
General Data Protection Regulation (GDPR)


- Regulates the processing by an individual, a company or an organisation of personal data relating to individuals in the EU. Personal data is any information that relates to an identified or identifiable living individual. Different pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data. Personal data that has been de-identified, encrypted or pseudonymised but can be used to re-identify a person remains personal data and falls within the scope of the GDPR. Personal data that has been rendered anonymous in such a way that the individual is not or no longer identifiable are no longer considered personal data. For data to be truly anonymised, the anonymization must be irreversible.
- The GDPR protects personal data regardless of the technology used for processing that data – it’s technology neutral and applies to both automated and manual processing, provided the data is organised in accordance with pre-defined criteria (for example alphabetical order). It also doesn’t matter how the data is stored – in an IT system, through video surveillance, or on paper.
Cybersecurity Act

Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (Text with EEA relevance)

- The Framework is based on voluntary certification schemes, which are risk based on ‘Assurance Levels’. The schemes specify the evaluation process relevant for specific product categories and their assurance levels. These Assurance Levels are representative of the level of the risk associated with the intended use of the ICT product, service or process, in terms of the probability and impact of an incident.

- The Assurance Levels are split into three categories: Basic, Substantial, High.

- The Commission will take on the responsibility of assessing the efficiency of the scheme after three years of its adoption. If found unsatisfactory, the Commission may propose a legislative act for the enforcement of mandatory requirements.
Useful links and references

• EU health policy: https://ec.europa.eu/health/policies/overview
• Medical devices sectoral website (to be transferred): https://ec.europa.eu/growth/sectors/medical-devices
• The ‘Blue Guide’ on the implementation of EU product rules: https://ec.europa.eu/docsroom/documents/18027
• CE marking: https://ec.europa.eu/growth/single-market/ce-marking/
• CEN-CENELEC Medical equipment: https://www.cen.eu/work/Sectors/Healthcare/Pages/Medicaequipment.aspx
Some questions along the medical device life-cycle

Dr. Georg Heidenreich
Siemens Healthcare GmbH

Co-Convenor JWG7

„Safe, effective and secure health software and health IT systems, including those incorporating medical devices”
Some questions along the medical device life-cycle

1. What is the relationship between Safety and Security?

2. CIA or AIC? Are medical devices in "office IT" or "factory IT"?

3. What’s foreseeable - when a manufacturer analyzes threats?

4. What is the perfect balance of safety, security and performance?

5. Will "process" or "product" matter more?

6. Assessment: "steep way" or "market enabler"?
What is the relationship between safety and security?
Information Security or Operations Security?
What is foreseeable (from the manufacturers’ perspective)?
Can we „reduce risks as far as possible” ?

EU MDR, Annex I GSPR, ch. 1, clauses 2 & 4a, p. 94, OJ 5.5.2017
Will we move from „product“ to „process“?
Appropriate certificates of successful assessment may support
Confidence in safety, security and effectiveness!

Regulation, standards and their assessment improve confidence in the use of technical systems!
Cybersecurity in medical devices

Dr. Abtin Rad
TÜV SÜD Product Service Division
Outlook

1. Challenges and why for Cybersecurity
2. Cyber Attacks
3. Health Care Data – Data Privacy
4. Reputational damage
5. Secure Solution - safe and secure development
6. Summary
Challenges and why for Cybersecurity?

- Approximately 1 of 4 medical devices are connected medical devices
- 125 billion devices connected to the internet by 2030 [1]

- Any (medical)-device incorporating software can be vulnerable to cybersecurity threats
  - Health related risks
  - Health care data privacy related risk
  - Economic risks
  - Reputational risk

“…Cyber-attacks pose more danger to democracies and economies than guns and tanks…”
Commission President Jean-Claude Juncker 2017
Cyber Attacks

Hospira infusion pumps attack

One Touch Ping insulin pump

WannaCry Ransomware

Source: [16]

Source: [15]

Source: [17]
83% of medical device manufacturers hacked at least once in 2019

Health Care Data – Data Privacy

Health Care Data contains most private information:
- Address, name, insurance information
- Medical conditions, diseases
- Drugs and therapies taken

2018: Singapore: Deliberate, targeted and well-planned cyber attack on SingHealth repeatedly targeted PM Lee's personal particulars and information on medicine that had been dispensed to him [11][12]

Medical device: Radiation therapy:
- Medical Product: no individual password
- Private internet router: with individual password
Reputational damage

Avoid being published here
Secure Solution & good coding principles

- MDCG publish new guidance to fulfil all relevant cybersecurity requirements in Annex I of MDR and IVDR (MDCG 2019-16)

- Section 3 specifies requirements on a Secure by design approach
  - Security Management
  - Specification of Security requirements
  - Secure by design
  - Secure Implementation
  - Secure verification and validation
  - Management of security-related issues
  - Security update management
  - Security guidelines
Secure Solution

- MDCG publish new guidance to fulfil all relevant cybersecurity requirements in Annex I of MDR and IVDR (MDCG 2019-16)
  - NIS directive to boost the overall cybersecurity within the European Union
  - GDPR covering individuals persona data in EU
  - Cybersecurity Act: Certification Scheme
Challenges on the market and practical steps

**Challenges on the market**
- Higher *classifications* of Class I medical device software
- Health apps are reimbursement by insurance companies (DE)
- Missing harmonized standards
- Increase interest of hackers on medical records and medical devices

**Best Practice steps**
- Consider: Cyber attacks don’t just happen to large companies
- Understand the treats
- Adopt a risk based approach
- Create a cyber risk management life cycle
- Be able to detect an attack
- Be prepared to react on incidences
- Challenge and test regularly
“As the level of threat is [...] critical for medical devices, more suitable Cyber Security mechanisms will have to be developed in the future.”

“We need to do our utmost to protect critical healthcare systems [...] and work towards improving the safety of the patients”

“Medical device manufacturers are responsible [...] about identifying risks and hazards [...] including [...] cybersecurity.”

Paris call for trust and Security in cyberspace in 2018 (French President Emmanuel Macron) endorsed by 64 countries
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Literature

Additions

1. Security management:
   1. 4.1 of ISO 13485, for the security risk management process
   2. 5.1 of IEC 62304: Software development plan
   3. 6.1 of IEC 62304: Software maintenance
2. Specification of Security Requirements:
   1. 5.2 of IEC 62304: software requirements analysis
3. Secure by design, including defense in depth:
   1. 5.3 of IEC 62304: software architecture
4. Secure implementation:
   1. 5.4 of IEC 62304: software detailed design
   2. 5.5 of IEC 62304: software implementation and unit verification
   3. and a precision on SOUP management
5. Secure Verification and Validation
   1. 5.6 of IEC 62304: software integration testing
   2. 5.7 of IEC 62304: software system verification
6. Management of security-related issues
   1. 6.2 of IEC 62304: Problem and modification analysis
   2. 9 of IEC 62304: Problem resolution
7. Security update management
   1. 6.3 of IEC 62304: Modification implementation
   2. 8.2 of IEC 62304: Change control
8. Security guidelines:
   1. 5.8 Software release
   2. and also software documentation, see IEC 82304-1 section 7.