MDCG 2019-16 Guidelines: Case Study-based Assessment and Path Forward

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Background & Motivation

- Cybersecurity is a key requirement for ensuring the safety and performance of Connected Medical Devices (CMDs).
- The MDCG 2019-16 guidance is an essential document, but feedback from real-world CMD deployments has revealed practical gaps.
- There is a growing need for clarity, completeness, and practical support in implementing the guidance across diverse healthcare environments.

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Aim of the Work

- To perform a case study-based assessment of the MDCG 2019-16 guidelines for cybersecurity in CMDs.
- To identify implementation challenges and unmet needs based on structured case studies input.
- To provide constructive, evidence-based recommendations for improving future iterations of the MDCG 2019-16 guidance.

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Our feedback to the MDCG is a joint effort

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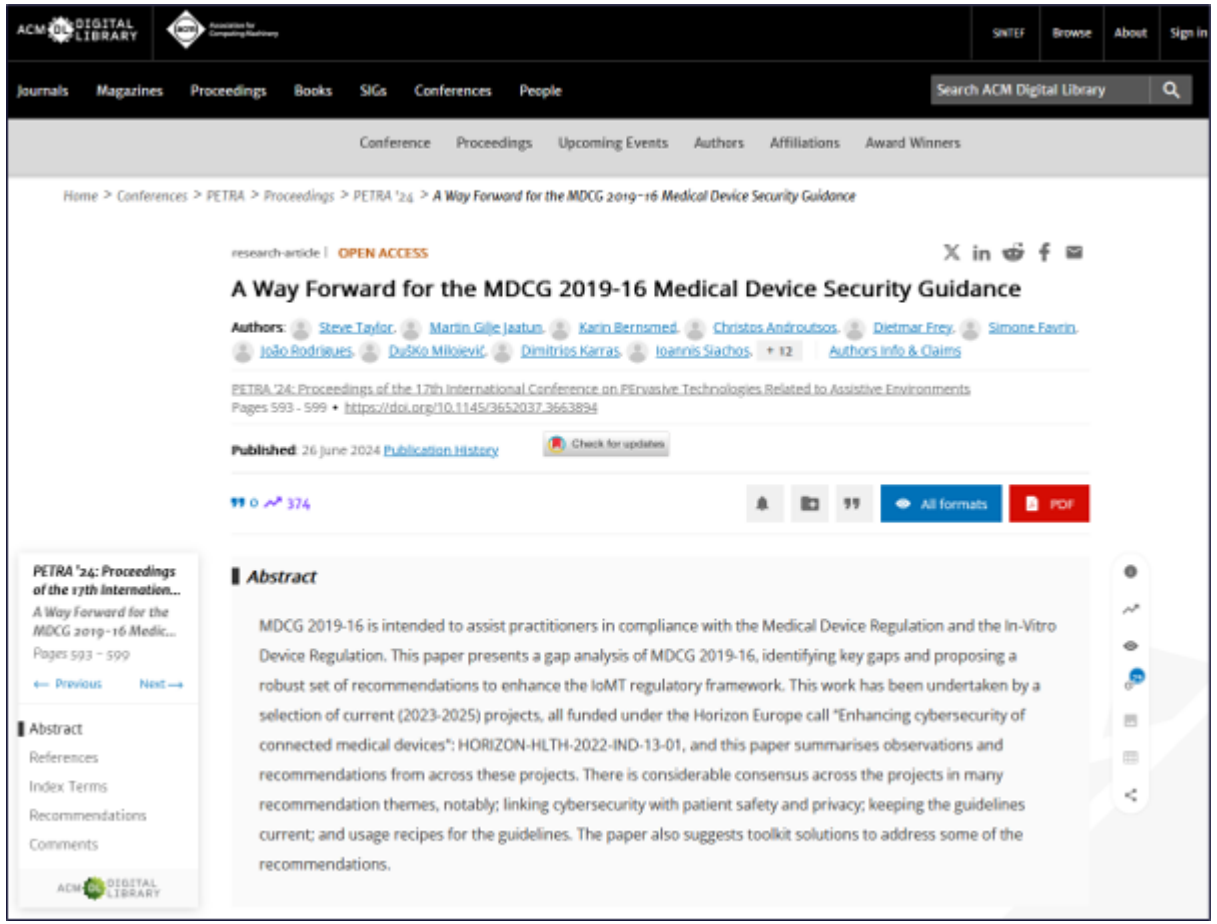

Taylor, S., Gilje Jaatun, M., Bernsmed, K., Androutsos, C., Frey, D., Favrin, S., ... & Katzis, K. (2024, June). A way forward for the MDCG 2019-16 medical device security guidance. In Proceedings of the 17th International Conference on PErvasive Technologies Related to Assistive Environments (pp. 593-599).

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Nemecys Case Studies

- **Re:Balans Patch Sensor:** A non-invasive wearable for hydration monitoring in dialysis patients, transmitting real-time data to external devices.
- **PDMonitor:** An IoT wearable for continuous monitoring of Parkinson's Disease across home and hospital settings.
- **Diabetes Management App:** A Class IIb mobile SaMD providing insulin dose advice based on patient input.
- **Freestyle Libre 2 CGM:** A continuous glucose monitoring kit integrating wearable sensors, readers, and web-based applications.

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SEPTON Case Studies

- **Implantable Medical Devices (IMDs):** Focus on seizure detection and secure data transmission to smartphones.
- **Wearable Devices for RPM:** Gathers health metrics and transmits them to cloud or hospital systems.
- **Hospital Infrastructure Security:** Includes PACS servers, MRI scanners, and critical imaging equipment.Distributed Health Systems: Uses blockchain and IPFS for secure, decentralized medical data sharing.

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MEDSECURANCE Case Studies

- **Remote Patient Monitoring (RPM):** Evaluates secure networked transmission of patient data.
- **Portable PCR Testing:** Addresses security in mobile testing under challenging field conditions.
- **Virtual Ward:** Simulates remote hospital ward management using CMDs and IT systems to evaluate integrated risk mitigation.

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CYLCOMED Case Studies

- **Hospital Equipment Pilot:** Collaboration with Hospital Niño Jesús to gather feedback on tool performance.
- **Telemedicine in Hospital Settings:** Active involvement of clinicians from hospitals in Rome, Berlin, and Madrid to validate tool usability and protocol alignment with real-world workflows.

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- **KardinBLU ECG Monitoring:** Multi-parameter Bluetooth system transmitting cardiological data via mobile or desktop devices.
- **Tellu Personal Health Gateway:** Gateway collecting home-based health data and transmitting it to a cloud-based eHealth platform.
- **Hospital Patient Care:** Demonstrators in smart ambulances and emergency units focus on CMD trustworthiness, especially for legacy systems.
- **Feel Emotion Sensor (FES):** A wearable used in digital mental health monitoring, capturing physiological data for biomarker analysis.

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CYMEDSEC Case Studies

- **CMD Vulnerability Mapping:** Reviews incidents involving vital monitors, pumps, and imaging systems using CVEs and FDA reports.
- **Hospital-at-Home Risk Analysis:** Evaluates MDCG and FDA guidance for adequacy in home-based care settings.
- **Baseline Checklist Comparison:** Independent benchmark created from NIST CSF 2.0, IEC 81001-5, AAMI TIR57, and BSI-03161 to identify regulatory gaps and scope alignment.

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Methodology

A structured Excel-based template was designed to enable a consistent and in-depth review of the guidelines and included the following components:

07 - Feedback

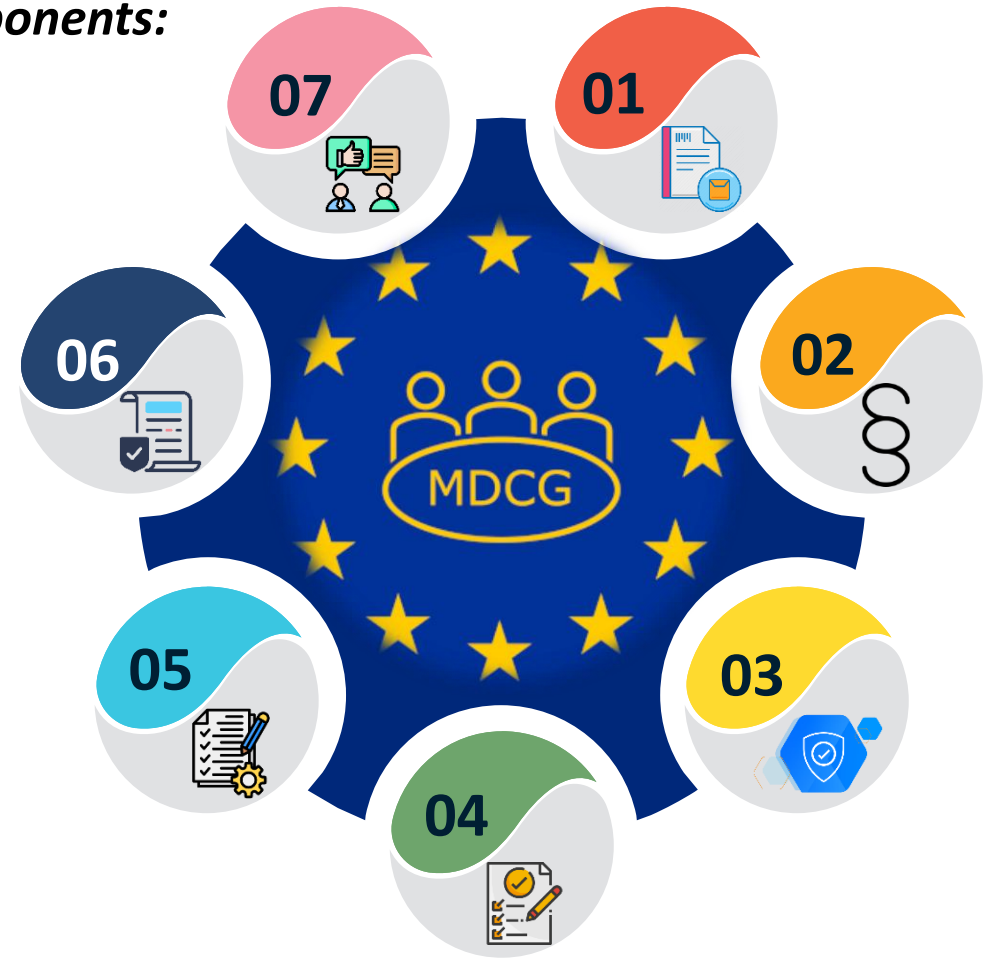
A field was included to collect observations and assessments from the case studies.

06 - Actual Guideline

Each guideline was outlined in detail, ensuring case study owners had the full text for review and analysis.

05 - MDR Requirements:

Alignment with key aspects of the Medical Device Regulation (MDR) was indicated, providing stakeholders with insights into the regulatory objectives the guidelines aim to address.



01 - Unique ID

Each guideline was assigned a unique identifier to enable traceability and simplify reference across the project's documentation and discussions.

02 - MDCG Section

The specific section of the MDCG 2019-16 guidelines from which each recommendation was derived, providing clarity and context for the reviewers.

03 - Defense-in-Depth Strategy

Specific guidelines were categorized based on the principles of defense-in-depth security strategies, reflecting the multi-layered approach required to protect CMDs against cybersecurity risks.

04 - IT Requirements Subcategory

Specific guidelines were further broken down into IT-related subcategories, such as basic principles and general security requirements for operating environments.

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Methodology

- Applied a structured stakeholder and case study approach using collaborative workshops and standardized templates.
- Identified MDCG gaps through observed tool limitations in mitigating practical risks.
- Stakeholder engagement in hospital settings through interviews with clinicians, IT staff, and data protection officers pre- and post-dashboard deployment.
- Focused on the impact of MDCG on clinical workflows, patient care, and ethical compliance.

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Methodology

- Developed a Trust Assessment Framework (TAF) as outlined in Section 2.4 (Vulnerability Management) of the MDCG 2019-16 guidelines.
- Refined threat lists and control strategies through use-case-specific questionnaires.
- Performed literature-based analysis of real-world Vulnerabilities and Exposures (CVE) and Common Weakness Enumeration (CWE) using Cybersecurity and Infrastructure Security Agency (CISA) and FDA sources to identify gaps and regulatory inconsistencies .
- Mapped existing cybersecurity incidents against MDCG 2019-16 and FDA guidance.

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MDCG 2019-16 Gap Analysis

01 Guidance Completeness

02 Terminology Clarity and Stakeholders' Responsibilities

03 Risk Management Framework

04 Verification and Validation

05 Defense-in-Depth Strategy

06 Safety vs Security

07 Medical Device Lifecycle Security

08 Post-Market Cybersecurity Maintenance

09 Secure Data Exchange

10 Human Factors in Cybersecurity

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MDCG 2019-16 Recommendations

Guidance Completeness

Consider **restructuring the guidance into a clearer and more practical format** that better supports manufacturers aiming for MDR compliance and CE marking.

Suggest **adding more detailed descriptions** on labeling, instructions for use, training protocols and validation processes.

Suggest clarifying how overlapping regulatory frameworks including **GDPR[1], NIS2 Directive[2], AI Act[3], and MDR[4], intersect and apply** within CMD contexts.

Introduce a **process for identifying domain-specific trust sources (e.g., digital twins, anomaly detection, attestation) to support trust assessment** in CMD deployment environments.

Recommend **evaluating available tools and proposing a practical toolkit** to support implementation (e.g., threat modeling, verification, patching, monitoring).

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[1] https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng
[2] https://digital-strategy.ec.europa.eu/en/policies/nis2-directive
[3] https://digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai
[4] https://eur-lex.europa.eu/eli/reg/2017/745/oj/eng

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MDCG 2019-16 Recommendations

Terminology Clarity and Stakeholders' Responsibilities

Suggest **referencing established frameworks (e.g.,** FDA Post market Management[1], FDA Cybersecurity in Medical Devices Guidance[2], ISO 14971[3], and AAMI TIR[4]) to enhance clarity.

Recommend **including a categorized list of common security requirements** to support manufacturers in drafting effective documentation.

Further clarity on the **distinctions** between **cybersecurity, security, and safety would enhance interpretation**, especially for wearable and IoT-based CMDs.

Definitions for cybersecurity terms such as **"layered defense" and "good security hygiene"** would **improve design consistency and stakeholder alignment.**

Propose incorporating **stakeholder-specific role guidance** for complex environments involving multiple actors (e.g., hospital-cloud systems, home-based monitoring)

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[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarket-management-cybersecurity-medical-devices
[2] https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity
[3] https://www.iso.org/standard/72704.html
[4] https://www.aami.org/detail-pages/product/aami-tir572016-r-2023-pdf-a152e000006j60wqaq

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MDCG 2019-16 Recommendations

Risk Management Framework

Include **requirements for detailed risk assessments** based on **real-world** use case scenarios, including the implementation of specific **mitigation measures and controls.**

Define **key terms, such as "reasonably foreseeable misuse"** in alignment with recognized standards like ISO 14971[1] and AAMI/TIR57:2016[2].

Provide documentation on **risk management best practices** and guidance on **performing risk-benefit trade-offs** where cybersecurity and clinical utility intersect.

Recommend a **tailored risk management approach for IoMT landscape**, including specific methodologies for assessing and mitigating risks.

Define a **top-down process to threat modeling**, beginning with general threats and adapting to specific infrastructure and domain-specific operational context.

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[1] https://www.iso.org/standard/72704.html
[2] https://www.aami.org/detail-pages/product/aami-tir572016-r-2023-pdf-a152e000006j60wqaq

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MDCG 2019-16 Recommendations

Verification & Validation

Include **illustrative examples of verification and validation testing processes** applicable to cybersecurity in medical devices.

Emphasize the use of **standardized templates for documenting verification and validation results** to promote consistency across stakeholders.

Strengthen **validation and verification processes** for higher-risk software categories.

Incorporate consideration of **human factors** during verification and validation and **align verification efforts** with the Clinical Evaluation Plan and Clinical Evaluation Report.

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Defense-in-Depth Strategy

Incorporate **practical examples and real-world scenarios** to clarify key concepts such as "layered defense," "depth approach," and "good security hygiene" within medical device cybersecurity contexts, **referencing certified technical ISO standards (e.g., ISO 27000 series)**

Provide **detailed descriptions**, including technical specifications, rational processes, and assessments that manufacturers should consider for **secure design.**

Explicitly **define requirements** for addressing **generic security-related threats**, with clear guidance on when specific security capabilities are necessary and how they apply to different device types and deployment contexts.

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Safety vs Security

Establish **"safety, security, and effectiveness" requirements** as integrated and measurable outcomes of a **systematic design and risk management process.**

Clearly **explain** the **relationship** between **safety risk assessments** (as addressed by ISO 14971[1]) and **security risk assessments** (e.g., TIR57[2]), especially when **security risks impact safety** and require traceability

Explicitly include **functional and non-functional IT** security requirements, aligned with the general safety and performance expectations outlined in **Annex I of the MDR.**

Establish minimum **cybersecurity baselines for legacy devices.**

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MDCG 2019-16 Recommendations

Medical Device Lifecycle Security

Include **IoMT-specific guidance** on secure coding practices, threat modeling, and continuous testing throughout the **software development lifecycle** to ensure robust cybersecurity for CMDs.

Define **minimum cybersecurity requirements** for mobile platforms that interface with medical wearables.

Emphasize the **need for manufacturer-validated security patches** to prevent unauthorized modifications or tampering during **deployment and maintenance phases.**

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Post-Market Cybersecurity Maintenance

Emphasize **structured post-market cybersecurity procedures**, including protocols for ongoing support, software maintenance, and mitigation of anticipated security degradation over time.

Define **clear processes** for vulnerability assessment, patch management, and regular security updates.

Introduce **specific protocols for secure over-the-air updates** to minimize the need for invasive procedures.

Provide **frameworks for dynamic trust assessment** in real-world deployment contexts, enabling the **identification of new threats and vulnerabilities** and the enforcement of the appropriate mitigation measures.

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Secure Data Exchange

Broaden the guidance to **include detailed strategies for data privacy management**, covering data consent, minimization, secure storage, and transmission protocols.

Introduce **standardized cybersecurity requirements for secure cross-institutional data sharing.**

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Human Factors in Cybersecurity

Integrate a human-centric approach into the guidelines and provide **targeted guidance on user awareness, training, and operational security practices** to strengthen the **prevention and mitigation of cyber threats** and improve stakeholder preparedness.

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Conclusions

- The outcome of this evaluation reinforces the important role of the MDCG 2019-16 guidelines in supporting cybersecurity assurance for medical device stakeholders.
- Across the participating projects, there is broad consensus that the guidelines are both useful and beneficial.
- These recommendations were presented to the MDCG New Technologies Working Group in Brussels..
- As a follow-up, we were provided with the editable Word version of the MDCG 2019-16 guidelines (Rev.1) to directly integrate our feedback.

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Thank you for your attention

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