

# Supplementary Material

**Table 1**

Table 1 creates, whenever feasible, a correlation between the 10 guiding principles identified by the FDA, Health Canada, and MHRA, and the relevant sections of the MDR [1], IVDR [2], ISO 13485 [3], IEC 62304 [4], IEC 82304-1 [5], as well as other relevant standards or guidelines.

About 50% of what is described in the FDA, Health Canada, and MHRA GMLP guiding principles document is reflected in Annex I of the MDR and IVDR, in point 7.3 (Design and Development) of ISO 13485, in point 5 (Software development process) of IEC 62304, and in point 4 (Health software product requirements) of IEC 82304-1. However, it is necessary to consider the contribution of other sections of the referred documents, such as Annex XIV – Part B (Post-market clinical follow-up) of the MDR, Annex XIII – Part B (Post-market performance follow-up) of IVDR, point 6 (Software maintenance process) of IEC 62304, or point 5 (Health software – software life cycle processes) of IEC 82304-1, as well as other standards or guides like ISO 14971, ISO/IEC 23894:2023, ISO 14155, or MDCG 2019-16 [1]–[10].

<b>Good Machine Learning Practice for Medical Device Development: Guiding Principles (US, Canada, UK) [9]</b>	<b>MDR/IVDR [1], [2]</b>	<b>ISO 13485 [3]</b>	<b>IEC 62304 [4]</b>	<b>IEC 82304-1 [5]</b>	<b>Other relevant standards or guides</b>
1 - Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	<u>Partially</u>  <b>MDR and IVDR:</b>  Article 10 - General obligations of manufacturers  Article 15 - Person responsible for regulatory compliance	<u>Partially</u>  6.2 - Human resources  7.3.2 - Design and development planning	---	---	ISO 14971 [7]  ISO/TR 24971 [11]  ISO/IEC 23894 [8]

2 – Good Software Engineering and Security Practices Are Implemented	<b>MDR and IVDR:</b>  Article 10  Annex I - General safety and performance requirements	7 - Product realisation	5 - Software development process  7 - Software risk management process	4 - Health software product requirements	ISO 14971 [7]  ISO/TR 24971 [11]  ISO/IEC 23894 [8]  IEC 62443-4-1 [12]  IEC 62443-4-2 [13]  IEC 81001-5-1 [14]  MDCG 2019-16 [6]  ISO/IEC 27000 series [15]
3 – Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	<b>MDR:</b>  Annex I  Chapter VI – Clinical evaluation and	7.3 - Design and development	<u>Partially</u>  5 - Software development process	4 - Health software product requirements  6 - Health software	ISO 14155 [10]

	<p>clinical investigation</p> <p>Annex XV – Clinical investigations</p> <p><b>IVDR:</b></p> <p>Annex I</p> <p>Chapter VI – Clinical evidence, performance evaluation and performance studies</p> <p>Annex XIV - Interventional clinical performance studies and certain other performance studies</p>			product validation	
4 – Training Data Sets Are Independent of Test Sets	<p><b>MDR:</b></p> <p>Annex I</p> <p>Chapter VI</p> <p>Annex XIV – Part A –</p>	7.3 - Design and development	5 - Software development process	<p>4 - Health software product requirements</p> <p>6 - Health software product validation</p>	<p>ISO 14155 [10]</p> <p>ISO/IEC TR 24027 [16]</p>

	<p>Clinical Evaluation</p> <p>Annex XV</p> <p><b>IVDR:</b></p> <p>Annex I</p> <p>Chapter VI</p> <p>Annex XIII – Part A - Performance evaluation and performance studies</p> <p>Annex XIV</p>				
5 - Selected Reference Datasets Are Based Upon Best Available Methods	<p><b>MDR and IVDR:</b></p> <p>Annex I</p>	7.3 - Design and development	5 - Software development process	4 - Health software product requirements	ISO/IEC TR 24027 [16]
6 - Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device	<p><b>MDR and IVDR:</b></p> <p>Annex I</p>	7.3 - Design and Development	5 - Software development process	4 - Health software product requirements	<p>ISO 14971 [7]</p> <p>ISO/TR 24971 [11]</p> <p>ISO/IEC 23894 [8]</p>

7 - Focus Is Placed on the Performance of the Human-AI Team	<u>Partially</u>  <b>MDR:</b>  Annex I  Chapter VII - Post-market surveillance, vigilance and market surveillance				
	Annex XIV – Part B - Post-market clinical follow-up  <b>IVDR:</b>  Annex I  Chapter VII - Post-market surveillance, vigilance and market surveillance  Annex XIII – Part B - Post-market performance follow-up	<u>Partially</u>  7.3 - Design and development  7.5 - Production and service provision  8.2.1 - Feedback	<u>Partially</u>  5 - Software development process  6 - Software maintenance process	<u>Partially</u>  4 - Health software product requirements  5 - Health software – software life cycle processes	---

8 - Testing Demonstrates Device Performance During Clinically Relevant Conditions	<b>MDR:</b>  Chapter VI  Annex XV  <b>IVDR:</b>  Chapter VI  Annex XIV	7.3.7 - Design and development validation	---	6.2 - Performing Validation	ISO 14155 [10]
9 - Users Are Provided Clear, Essential Information	<b>MDR and IVDR:</b>  ANNEX I, Chapter III - Requirements regarding the information supplied with the device	7.2.3 a) - Product information	---	7 - Health software product identification and accompanying documents	ISO 15223-1 [17]  ISO 20417 [18]
10 - Deployed Models Are Monitored for Performance, and Re-training Risks Are Managed	<b>MDR:</b>  Chapter VII  Annex XIV – Part B  <b>IVDR:</b>  Chapter VII	8.2.1 - Feedback	6 - Software maintenance process	8 - Post-market activities for the health software product	ISO 14971 [7]  ISO/TR 24971 [11]  ISO/IEC 23894 [8]

	Annex XIII – Part B				
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## References

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- [10] “ISO 14155:2020 - Clinical investigation of medical devices for human subjects - Good clinical practice.” 2020. Accessed: Dec. 08, 2023. [Online]. Available: <https://www.iso.org/standard/71690.html>

- [11] "ISO/TR 24971:2020 - Medical devices - Guidance on the application of ISO 14971." 2020. Accessed: Dec. 08, 2023. [Online]. Available: <https://www.iso.org/standard/74437.html>
- [12] "IEC 62443 4 1:2018 - Security for industrial automation and control systems - Part 4-1: Secure product development lifecycle requirements."
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