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The New Rules forAI in MedTech

A Practical Guide to the EU AI Act, the MDR/IVDR Simplification Proposal, and the Digital Omnibus

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1. Introduction

Artificial intelligence has long become part of the regulatory day-to-day in medical technology. What is frequently underestimated, however, is not the technological complexity but the regulatory entanglement that results from it.

AI-enabled software no longer operates within a single legal framework. It is simultaneously subject to the MDR or IVDR and increasingly falls within the scope of the European AI Act. This does not create a parallel coexistence but rather a regulatory interplay with direct implications for classification, development, documentation, and post-market surveillance.

It is precisely at this intersection that the critical practical questions arise: When does AI software qualify as a medical device at all? Which criteria lead to classification as a high-risk AI system? And how do the requirements of the MDR/IVDR and the AI Act concretely interact?

This paper structures the subject along these lines of inquiry. It begins with the regulatory foundations, proceeds through the classification framework, and then examines the practical interplay between the regulatory regimes. Current developments at the European level are also assessed and translated into concrete courses of action.

The objective is not an abstract presentation of the legal position, but a reliable orientation for practical implementation.

2. Basics KI Software under MDR and IVDR

2.1 What is Medical Device Software (MDSW)?

The central starting question in any regulatory assessment of AI software is not technical in nature, it is regulatory:

Does the software constitute a medical device or an in vitro diagnostic at all? The classification is determined not by the technology employed, but exclusively by the **intended purpose.**

Under Article 2 MDR, a medical device is any instrument, apparatus, implant, or software intended by the manufacturer for one or more medical purposes, including, in particular, the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease or injury.

The IVDR definition in Article 2 is more specific. The software must not only be intended for the examination of specimens, but must specifically aim to provide information, for example, concerning physiological or pathological processes, congenital anomalies, and similar matters.

The decisive test is therefore clear:
not every software application in healthcare is automatically subject to the MDR or IVDR. Only a defined medical intended purpose triggers regulatory classification.

If an AI application meets these criteria, it qualifies as a medical device or IVD with the consequence that the full regulatory requirements of the relevant regulation apply.

In practical application, this distinction can be illustrated by reference to typical scenarios:

- **Clear MDR case:**
  An AI algorithm analyses X-ray images and identifies lung tumors, providing a diagnostic recommendation to the radiologist. The intended purpose clearly lies in the diagnosis of a disease. → Classification as a medical device under the MDR.
- **Clear IVDR case:**
  Software evaluates PCR data and interprets the Ct value with regard to the presence of an infection. The intended purpose relates to the examination of body specimens for diagnostic purposes. → Classification as an IVD under the IVDR.
- **Regulatory grey area:**
  An AI application calculates risk scores for hospitalization on the basis of patient data. What is decisive here is not the data source but the intended use: If the score is used to support clinical decisions, a medical intended purpose may exist. If the use is exclusively for administrative or organizational purposes, the software does not constitute a medical device.

It is precisely these grey areas that regularly give rise to misclassification in practice, frequently because the functionality of the software is conflated with its regulatory intended purpose.
For the structured assessment and delineation of software, the MDCG Guidance 2019-11 (in its current version) provides a well-established and practically proven reference point.

2.2 Classification of AI Software under MDR and IVDR

Once an AI application has been qualified as a medical device or in vitro diagnostic, the next step is classification.
Classification is the central regulatory lever, as it directly determines which conformity assessment procedure applies and whether a Notified Body must be involved.

For software under the MDR, **Rule 11 in Annex VIII** is of particular relevance.
The logic of this rule is risk-based and is anchored **in the potential impact of the information provided by the software on clinical decisions:**
Software that provides information for diagnostic or therapeutic decisions is generally assigned at least **Class IIa**.

If a potential misinterpretation could lead to a serious deterioration in the patient's health or to surgical intervention, classification in **Class IIb** applies.
Where there is a risk of death or irreversible harm to health, classification in **Class III** is required.

This shifts the assessment away from pure functionality towards the **clinical relevance of the** decision influenced by the software.

The practical consequence is clear: the majority of AI-enabled software in diagnostic or therapeutic contexts falls at least into Class IIa, frequently higher, and therefore requires the involvement of a Notified Body.

Under the IVDR, classification follows the classes **A, B, C, and D,** likewise along a risk-based approach.
The decisive criteria are, in particular:

- the significance of the test result for individual patient care, and
- the potential risk to public health.

Typical classifications for AI-enabled software are:

Class C:

Software supporting diagnostic decisions, for example in the context of companion diagnostics or the interpretation of clinically relevant laboratory parameters.

Class D:

Applications of high relevance for critical diagnoses, for instance, in the context of infectious diseases posing a significant risk to public health, or safety-critical blood testing.

Here too:
from Class B onwards, and therefore practically always for relevant AI applications, involvement of a Notified Body is required.

Classification under the MDR or IVDR has an immediate consequential effect beyond medical device law. It forms the basis for assessing whether an AI application must additionally be classified as a **high-risk AI system** within the meaning of the AI Act.
This link is not a formal ancillary consideration but a structural element of the future regulation of AI in healthcare and it is precisely here that the actual interplay between the regulatory frameworks begins.

The classification rules, including Rule 11 in particular, are currently under discussion and amendments have been proposed.

2.3 Core Requirements: What MDR/IVDR Demand from AI Systems

Once qualification and classification have been established, the regulatory framework is set. The actual demonstration of conformity, however, occurs through the **General Safety and Performance Requirements (GSPR)** set out in Annex I of the MDR or IVDR.

These requirements apply irrespective of the technology used. For AI systems, the challenge arises from the fact that **the nature of risk generation and performance assessment shifts fundamentally.**

Risk management under EN ISO 14971 remains the central methodological framework. For AI systems, however, the risk spectrum expands considerably. Alongside classical risks such as malfunctions or system failures, data- and model-related risks come prominently to the fore:

Bias: Systematic distortions caused by non-representative or flawed training data

Concept Drift: Degradation in model performance as a result of changing real-world conditions

Overfitting: Strong performance on training or test data coupled with insufficient generalizability.

These risks must not be viewed in isolation as purely technical matters, they must be translated into a regulatory context:

The clinical evaluation (MDR) or performance evaluation (IVDR) must demonstrate that the software fulfils its intended purpose under real-world conditions of use. For AI systems, the focus shifts considerably: performance depends directly on the quality, representativeness, and stability of the underlying data.

This gives rise to two central challenges:

- Demonstrating that training and validation data adequately represent the target population
- Ensuring that system performance remains stable outside controlled testing environments

As a result, for AI systems the clinical evaluation effectively becomes an **assessment of the data basis and its transferability to clinical reality.**

The requirements for software lifecycle processes, in particular under IEC 62304, continue to apply.

For AI systems, however, a classical, static perspective is insufficient. The central question is how to control a system whose behavior is substantially shaped by data and may potentially change over time.

Additionally relevant are:

- the application of EN ISO 14971 to software (IEC/TR 80002-1), and
- future requirements for AI-specific management systems, for instance in the context of ISO/IEC 42001

What matters is not the existence of individual processes in isolation, but their interplay: **risk management, clinical/performance evaluation, and the software lifecycle must all build consistently on the same shared understanding of the AI system.**

3. The EU AI Act – A New Regulatory Framework for AI

3.1 Overview and Timeline of the AI Act

The AI Act establishes for the first time a standalone European legal framework for artificial intelligence. Regulation (EU) 2024/1689 entered into force on 1 August 2024 and follows a cross-sectoral approach. It therefore also addresses AI systems in healthcare, irrespective of whether those systems are already subject to the MDR or IVDR.

Implementation proceeds in stages according to a staggered timeline:

2 February 2025:

Entry into force of the prohibitions on AI systems posing unacceptable risk under Article 5, and first requirements on AI competence under Article 4

2 August 2025:

Obligations begin for providers of General Purpose AI (GPAI) models under Chapter V

2 August 2026:

Applicability of the core requirements for high-risk AI systems under Chapter III, with the exception of certain specific systems

2 August 2027:

Extended application to further high-risk AI systems, in the context of Annex I

This timeline represents the formal structure of the rollout. In practical implementation, however, it is important to note that individual deadlines and scopes are already subject to regulatory evolution. Adjustments may arise in connection with current simplification initiatives.

For manufacturers, this means:
the requirements do not become relevant only at the respective cut-off dates. They must be factored into strategic and technical decisions today. It is equally important to remain up to date, as the deadlines may still shift as a result of current legislative proposals.

3.2 The Risk-Based Approach: Four Risk Categories

The AI Act follows a clearly structured, risk-based approach. The higher the potential risk of an AI system to health, safety, or fundamental rights, the more comprehensive the regulatory requirements.

The AI Act distinguishes four risk categories:

- **Unacceptable risk:**
  AI systems that violate fundamental rights or operate manipulatively are prohibited in principle. Examples include social scoring or certain forms of targeted behavioral manipulation. In practice, this category plays only a minor role in medical technology.
- **High risk:**
  This category forms the core of the AI Act. High-risk AI systems are subject to comprehensive requirements relating, among other things, to risk management, data quality, transparency, documentation, and conformity assessment.
- **Limited risk:**
  Systems with limited risk are subject primarily to transparency obligations, for instance, where users must be informed that they are interacting with an AI.

- **Minimal risk:**
  No specific regulatory requirements apply to these systems beyond general legal provisions.

For medical technology, however, this classification is less open than it first appears. A structural mechanism in the AI Act is decisive:
AI systems that are regulated as medical devices or in vitro diagnostics and are subject to a conformity assessment by a Notified Body are generally automatically classified as high-risk AI systems.
As a result, this classification is not primarily a discretionary risk assessment, it follows from the existing regulatory framework established by the MDR and IVDR.

The practical consequence is clear: the majority of AI-enabled software in medical contexts falls not by chance, but systematically, into the "high risk" category.

3.3 When Is an AI Medical Device a High-Risk AI System?

The central question at the intersection of the MDR, IVDR, and AI Act is:
under what conditions does an AI medical device additionally qualify as a high-risk AI system?

Article 6(1) of the AI Act defines a two-stage decision mechanism for this purpose.

Stage 1: Integration into existing EU harmonization legislation

First, it is assessed whether the AI system:

- is itself a product or a component of a product, and
- falls under one of the EU legislative instruments listed in **Annex I of the AI Act**

These instruments include, among others, the MDR and IVDR. The first condition is therefore generally satisfied for AI systems in a medical context.

Stage 2: Conformity assessment by a third party

In the second step, the decisive question is how the product is assessed from a regulatory perspective.

An AI system falls into the high-risk category where the underlying product requires a conformity assessment involving a Notified Body.

This gives rise to the following practical logic:

- **MDR:**
  Classes IIa, IIb, and III → generally high-risk AI systems
- **IVDR:**
  Classes B, C, and D → generally high-risk AI systems

Conversely:

- **MDR Class I** or **IVDR Class A** without Notified Body involvement generally **does not** lead to classification as a high-risk AI system under Article 6(1), even where the system is technically an AI system.

Practical Implications

An important point of interpretation: classification as a high-risk AI system is not a separate, freely conducted risk assessment. It follows from the existing regulatory classification of the product.
In practice, this produces a clear pattern: as soon as an AI system in a medical context fulfils a relevant clinical function and is classified accordingly, it will typically also fall within the scope of the AI Act's high-risk regulation.

Examples:

- **AI radiology software (MDR Class IIa, Notified Body required):**
  → High-risk AI system
- **AI-based PCR analysis algorithm (IVDR Class C):**
  → High-risk AI system
- **AI application for general health guidance without a medical intended purpose:**
  → Not a high-risk AI system under Article 6(1), however, classification under other risk categories of the AI Act should be examined

3.4 Requirements for High-Risk AI Systems

Where an AI system is classified as a high-risk AI system, the requirements of Chapter III, Section 2 of the AI Act (Articles 8 to 15) apply.

At first glance, this may appear to constitute an entirely new regulatory framework. In practice, however, a more nuanced picture emerges: many of these requirements are already familiar to medical device manufacturers from the MDR and IVDR. The real challenge lies less in new subject matter than in **the specific way these requirements are expressed for AI systems.**

Risk management system (Article 9)

The AI Act requires continuous risk management throughout the entire lifecycle of the AI system.

For MedTech manufacturers, this is not a new concept, the requirements of EN ISO 14971 continue to form the foundation. What is new, however, is the explicit focus on AI-specific risks, in particular those relating to data dependency, model behavior, and system dynamics.

Data and data governance (Article 10)

This article is among the most demanding in the entire framework.

Training, validation, and test data must be appropriate, representative, and free of systematic errors. Known or foreseeable biases must be identified and addressed.

For medical technology, this represents a significant shift: whereas under the MDR and IVDR data is considered primarily in the context of clinical evaluation, the AI Act places the **quality and suitability of the data basis** itself at the center of regulatory assessment.

Technical Documentation (Article 11)

The requirements for Technical Documentation are familiar in their basic structure. However, the AI Act broadens the focus: in addition to the classical description of design, function, and risk, **the model logic, data provenance, and system behavior** must now be documented in a traceable manner. This makes the Technical Documentation more clearly an instrument for rendering the workings of data-driven systems transparent.

Logging (Article 12)

High-risk AI systems must be capable of automatically recording relevant events during operation.

This requirement complements existing monitoring and vigilance frameworks. It creates the basis for understanding system behavior in the field and identifying deviations at an early stage.

Transparency (Article 13)

The system must be designed such that users can appropriately interpret its outputs.

For medical technology, this is not an entirely new expectation, but it is now considerably more specific: a purely functional "black box" without traceable decision logic is increasingly difficult to defend from a regulatory standpoint.

Human oversight (Article 14)

The AI Act requires that high-risk AI systems can be effectively overseen by humans.

This encompasses not only organizational measures but also the technical design of the system itself. Users must be able to question, correct, or, if necessary, disregard system outputs.

In this way, the AI Act specifically addresses the risk of so-called **automation bias**, the uncritical acceptance of AI-generated results.

Accuracy, robustness, and cybersecurity (Article 15)

The system must achieve an adequate level of accuracy, robustness, and security. For AI systems, this means in particular:

- Stability in the face of varying input data
- Controlled behavior in the event of errors or disruptions
- Protection against deliberate manipulation, for example through adversarial attacks

Clear parallels with existing MDR and IVDR requirements exist here as well. The difference lies in the stronger focus on the specific characteristics of data-driven systems.

Practical Implications

The AI Act does not introduce a wholly new quality or risk management system. It refines existing requirements and specifically extends them to address AI-specific aspects.

For manufacturers, this means:
the challenge is not to build a second system, but to develop existing processes in a way that does justice to the particular features of AI systems.

4. The Interplay in Practice – MDCG 2025-6

As the MDR, IVDR, and AI Act become increasingly intertwined, manufacturers face a central challenge: the individual regulatory requirements are each clearly defined, but their **practical interaction** has for a long time remained undefined.
It is precisely at this point that the guidance **MDCG 2025-6 / AIB 2025-1**, published in June 2025, comes into play.

This is a joint document of the Medical Device Coordination Group and the AI Board, entitled
"FAQ on Interplay between the Medical Devices Regulation & In vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act".

The significance of this guidance lies less in introducing new regulatory requirements than in its function as an **interpretive framework**:
It answers key questions on the parallel application of the regulatory regimes and thereby provides for the first time a consistent basis for classifying AI systems in a medical context.

The FAQ-based approach is deliberately practice-oriented. Rather than offering abstract interpretation, the guidance provides concrete answers to typical questions arising from day-to-day implementation.

For manufacturers, this means: the guidance does not replace statutory requirements, **but it substantially defines how those requirements are to be understood and applied in combination.**
The following sections address the central statements of the guidance and contextualize them in terms of practical implementation.

4.1 Integrated Conformity Assessment – No Separate Procedure

One of the central statements of MDCG 2025-6 is also one of the most practically significant: for AI medical devices, no separate conformity assessment procedure under the AI Act is required.

Article 43(1) of the AI Act makes clear that for AI systems that form part of products falling under the MDR or IVDR, the conformity assessment is carried out within the framework of the existing procedures.

This means:
the Notified Body assessing the medical device simultaneously examines the relevant AI Act requirements.

In practice, this produces an integrated structure:

- One certificate from the Notified Body

- Technical Documentation supplemented with AI-specific content
- A single conformity assessment procedure covering both MDR/IVDR and AI Act requirements

This integration does not, however, reduce the substantive demands. The AI Act introduces additional elements of scrutiny into the existing procedure, in particular with regard to data, model behavior, and system transparency.

Practical Implications

There is no second procedure, but there are expanded requirements within the same procedure.

Important caveat: availability and competence of Notified Bodies

A critical issue currently lies in the implementation by Notified Bodies.

To be able to assess high-risk AI systems under the AI Act, Notified Bodies must demonstrate and expand their competencies accordingly. The relevant requirements are set out in Article 31 and Article 43(4), (5), (10), and (11) of the AI Act.

This process of building competency is still under development.

For manufacturers, this gives rise to a concrete recommendation: clarify early on whether and when your Notified Body will be able to assess AI systems under the AI Act.

4.2 Integrated QMS and Technical Documentation

MDCG 2025-6 specifies how existing MDR/IVDR structures can be used to reflect the requirements of the AI Act. The focus is not on a new documentation system, but on the **targeted extension of existing content**.

The Technical Documentation remains the central instrument of conformity assessment.

However, its character is changing:
it no longer serves merely to describe a system, but increasingly **to demonstrate that a data-driven system is understood and controlled in its behavior.**

The following elements illustrate where this extension concretely applies:

Area	MDR/IVDR Requirement	AI Act Addition
System description	General description of the product	Detailed description of the AI architecture, model type, and hyperparameters
Data	Clinical data for performance demonstration	Training, validation, and test data: provenance, volume, representativeness, bias analysis

Risk management	ISO 14971	AI-specific risks: bias, concept drift, adversarial attacks, overfitting
Performance evaluation	Clinical evaluation / performance evaluation	AI performance metrics (e.g. AUC, sensitivity, specificity), subgroup analyses
Post-market surveillance	PMCF / PMPF	Continuous algorithmic performance monitoring
Transparency	Instructions for use	Explanation of AI outputs, guidance on human oversight

Practical Implications

The table does not reveal new, isolated requirements, rather, it reflects a clear shift in the level of detail and focus expected from existing documentation.

Three patterns stand out in particular:

From function to system understanding:
It is no longer sufficient to describe what a system does. Manufacturers must demonstrate how the system arrives at its outputs and under what conditions this behavior may change.

From data as evidence to data as risk factor:
Where MDR/IVDR treat data primarily in the context of performance evaluation, the AI Act makes data itself the central subject of assessment.

From static evaluation to continuous monitoring:
Post-market activities shift from reactive surveillance toward active monitoring of system performance in the field.

For manufacturers, this means: the challenge is not to create additional documents, but to extend existing structures so they can capture the dynamic nature of AI systems.

4.3 Data and Data Governance: The Central Challenge

Data is central to assessment under both the MDR/IVDR and the AI Act. However, the regulatory focus differs fundamentally.
Under the MDR and IVDR, data is considered primarily **in the context of clinical or analytical performance evaluation**. It serves as evidence that a product is safe and achieves its intended performance.

The AI Act significantly extends this perspective. Article 10 shifts attention not just to the result, but to the quality and suitability of the data basis itself.

Concretely, this means:
training, validation, and test data must be constructed in such a way that they

adequately represent the target population and do not contain systematic biases that could lead to erroneous or discriminatory outcomes.

This creates a clear regulatory shift:

Data is no longer merely evidence; it is itself the subject of conformity assessment.

Practical example

A frequently cited example is AI-enabled skin cancer diagnostics.
Early systems were in some cases trained on datasets consisting predominantly of light-skinned patients. The consequence was a significantly lower detection rate for darker skin tones.
From a regulatory perspective, this is not merely a technical problem, it has direct implications:

- Under MDR/IVDR, the question arises as to whether clinical performance has been demonstrated for the entire target population at all.
- Under the AI Act, the additional question is whether the underlying data basis is appropriate and sufficiently representative.

Both perspectives lead to the same conclusion, but from different directions.

Practical Implications

For manufacturers, the consequence is clear: the selection, preparation, and evaluation of data becomes a central component of regulatory strategy.

It is no longer sufficient to demonstrate performance data. It must be transparently explained **why the data are appropriate for representing the real-world application scenario.**

This applies in particular to:

- the definition of the target population
- the composition of training and validation data
- and the handling of identified biases

4.4 Human Oversight and Transparency

Article 14 of the AI Act requires that high-risk AI systems be designed in such a way that they can be effectively overseen by humans.
In the medical context, this means concretely: the user must be able to understand, interpret, and where necessary question or override the system's outputs.
Human oversight is therefore not merely an organizational requirement; **it is a fundamental design specification for the system itself.**

This requirement has a direct bearing on the design of the user interface and documentation:

- The system must clearly communicate that its output constitutes an AI-supported recommendation, not a definitive medical decision.

- Users must be technically and functionally enabled to question, disregard, or correct results.
- The instructions for use must clearly describe the system's limitations, its assumptions, and potential areas of uncertainty.

This makes the user interface and instructions for use central elements of risk control, not merely downstream documentation artefacts.

The regulatory expectation is clearly stated. Practical implementation is considerably more demanding.

Numerous studies show that users tend to accept AI-generated results even when those results are erroneous. This phenomenon is described as **automation bias**.

A structural tension therefore arises: even a formally correctly designed system can lead to incorrect decisions in practice if users fail to critically scrutinize its outputs.

Practical Implications

For manufacturers, this creates a clear responsibility:
Human oversight must not simply be assumed. It must be actively supported and enabled through system design.
This applies in particular to:

- the way in which results are presented
- the integration of uncertainty indicators or confidence metrics
- and the deliberate avoidance of design choices that encourage uncritical use

4.5 Substantial Modifications to the AI System

A particularly practice-relevant aspect in dealing with AI systems is the question of when changes to the system trigger a new conformity assessment.

Under both the MDR/IVDR and the AI Act, the general principle applies: **substantial modifications to the system require a fresh assessment.**
While this logic is well established in classical medical device law, it takes on a new dynamic in the context of AI systems.

AI systems are frequently not static. They are further developed, retrained, or adapted to new data.

This is precisely where the central challenge arises: not every change is regulatorily relevant, but every change must be assessed to determine **whether it affects safety, performance, or intended purpose.**

Retraining is a typical example: retraining a model on new data may constitute a substantial modification but need not necessarily do so.

What is decisive:

- Does the system's behavior change significantly?
- Does this affect clinical performance or the risk profile?

Only when these questions are answered affirmatively does a substantial modification exist.

The requirements of the MDR/IVDR and the AI Act are not to be considered separately in this context. A modification that qualifies as substantial under MDR/IVDR will generally also be relevant under the AI Act, and vice versa.

For manufacturers, this means: the assessment of changes must in future **simultaneously take into account both regulatory perspectives.**

MDCG 2025-6 highlights that so-called **Predetermined Change Control Plans (PCCPs)** can play a central role.

A PCCP defines in advance:

- which changes are permissible
- within what parameters they may occur
- and under what conditions no new conformity assessment is required

This approach seeks to reconcile the flexibility that AI systems require with regulatory requirements.
The concrete design of such frameworks is still under development, particularly in the context of international approaches such as those of the IMDRF.

Practical Implications

For manufacturers, the consequence is clear:
Changes to AI systems can no longer be viewed in isolation as purely technical matters. They are an integral component of regulatory strategy.
This applies in particular to:

- the handling of training data and model updates
- the definition of change boundaries
- and the early planning of PCCP-type frameworks

Timing consideration

MDCG 2025-6 notes that certain obligations relating to substantial modifications for AI systems already placed on the market do not apply until 2 August 2027.
This creates a limited window of time. It should not, however, be understood as a deferral, but rather as an opportunity to build the necessary processes in good time.

5. The Planned Changes- MDR/ IVDR 2.0 and the Digital Omnibus

5.1 The MDR/IVDR Simplification Proposal (December 2025)

With the proposal COM(2025) 1023 final published in December 2025, the European Commission initiated a comprehensive revision of the MDR and IVDR.

The proposal is already widely referred to in the industry as “MDR 2.0” and “IVDR 2.0”, or simply “the Proposal”.

Formally, however, it does not constitute new regulations, it represents a targeted evolution of the existing frameworks.

The background is clear:
the current regulatory requirements have in practice led to significant bottlenecks, particularly with regard to the availability of Notified Bodies, the duration of conformity assessments, and market accessibility for products.

The Proposal addresses these challenges with three central objectives:

- Reducing administrative complexity
- Promoting innovation
- **Ensuring the supply of medical devices without compromising patient safety**

Structurally, the Proposal comprises several blocks of amendments affecting different legislative instruments:

- **Article 1:** Amendments to the MDR (Regulation (EU) 2017/745)
- **Article 2:** Amendments to the IVDR (Regulation (EU) 2017/746)
- **Article 3:** Amendments to the HERA Regulation (Regulation (EU) 2022/123)
- **Article 4:** Amendments to the AI Act (Regulation (EU) 2024/1689)
- **Article 5:** Provisions on entry into force

This structure already demonstrates that these are not isolated adjustments. The Proposal deliberately intervenes in the interplay between the existing frameworks, and thereby also addresses the interfaces between the MDR, IVDR, and AI Act.
The following sections examine the changes of particular relevance for AI systems in greater detail.

5.2 Adjustment of the classification rule for software

Classification Rule 11 in Annex VIII of the MDR has, since its introduction, been one of the central drivers of the regulatory classification of software. In its current interpretation, it results in the majority of medical software being assigned at least to Class IIa.

For AI systems, this has a direct consequence: **the involvement of a Notified Body becomes the rule and with it, classification as a high-risk AI system under the AI Act.**

Planned change

The current Commission Proposal envisages a fundamental revision of this logic.

Software with a medical intended purpose would **in principle be classified as Class I**. A higher classification would only apply where the software is used in applications associated with elevated risk, for instance, where it has a direct impact on therapeutic decisions in serious disease states.

This would shift the approach from a blanket upward classification towards a more **differentiated, risk-oriented assessment**.

However, the formulation in the Proposal is the subject of extensive discussion, as it is widely assumed in practice that a Class I classification would effectively be excluded in most cases.

Impact on AI systems

For AI-based software, this change would have an immediate consequential effect:

- **Class I generally implies no Notified Body involvement.**
- This would remove the automatic classification as a high-risk AI system under Article 6(1) of the AI Act.

For certain applications, this could lead to a significant reduction in regulatory burden.

Critical assessment

The proposed adjustment is not without controversy.

Critics point out that a broader opening towards Class I could give rise to new demarcation problems. In particular, the question of when an application still qualifies as "non-critical" and when it requires a higher classification remains open to interpretation.

There is therefore a risk that existing challenges are not resolved but merely displaced.

The final design will depend substantially on the further legislative process.

Practical Implications

For manufacturers of AI systems, this development means above all one thing: the close coupling between MDR classification and AI Act risk classification remains in place, but its practical effects may change significantly.

5.3 Cybersecurity as a regulatory interface

The proposed amendments significantly strengthen one aspect that has frequently been considered in isolation within the overall regulatory picture: cybersecurity.

The introduction of specific requirements in the form of new articles (MDR: Article 87a, IVDR: Article 82a) and the explicit anchoring of cybersecurity in the General Safety and Performance Requirements represent more than a mere addition of technical detail requirements.

What emerges for the first time is a systematic link between the vigilance system of the MDR/IVDR and the European structures for addressing IT security incidents.

Concretely, this means: manufacturers will in future be required not only to report classical serious incidents, but also to actively notify actively exploited vulnerabilities and security-relevant events to the competent cybersecurity structures, in particular CSIRTs and ENISA.

This fundamentally shifts the perspective on safety.

Whereas the MDR and IVDR have traditionally focused on the safety and performance of a product in a clinical context, the new provisions additionally address the integrity and resilience of the underlying digital systems.

This development is of central importance, particularly in the context of AI-based or software-driven medical devices.

Such systems are typically:

- data-driven,
- connected, and
- in many cases continuously learning or adaptive.

They are therefore subject not only to classical product safety-related risks, but also to dynamic threat scenarios from the field of IT security.

The result is a multi-dimensional regulatory perspective that can no longer be reduced to a single regulatory framework.

Manufacturers will in future operate within a field of tension encompassing:

- product safety and performance (MDR/IVDR),
- algorithmic risk assessment (AI Act), and
- IT security and system resilience (Cyber Resilience Framework).

This three-way structure changes not only the regulatory requirements, but also the internal organization of manufacturers. Security assessments can no longer be conducted in isolation within classical quality or regulatory functions, they require close integration with IT security expertise and, where applicable, with external reporting and response structures.

Cybersecurity is thereby elevated from a supporting topic to an integral component of overall regulatory responsibility.

5.4 Article 4 of the Proposal: the amendment to the AI Act

The central intervention of the Proposal does not occur within the MDR or IVDR themselves, but directly in the AI Act.

Article 4 of the Proposal fundamentally alters the structure of Annex I of the AI Act:

The MDR and IVDR are **removed from Section A of Annex I** and placed in **Section B**.

At first glance, this appears to be a technical adjustment. In practical effect, however, it **represents a paradigm shift in the regulatory linkage**.

What changes from a regulatory perspective?

Under the current regime:

AI systems falling under the MDR or IVDR that satisfy the conditions of Article 6 are classified as high-risk AI systems and are directly subject to the requirements of Chapter III of the AI Act.

With the move to Section B, this logic changes.

For these systems, the Chapter III requirements no longer apply directly on the basis of the listing in Annex I but will in future be addressed through the respective sector-specific frameworks.

The legal mechanism for this is Article 2(2) of the AI Act: for products falling under Section B, the extensive high-risk requirements of Chapter III are exempted from direct application.

What does this mean in practice?

The decisive consequence is:

The requirements of the AI Act do not disappear, **but they change their regulatory point of attachment.**

In future, central elements such as:

- Data Governance
- Transparency
- Human Oversight
- Robustness and Performance

are no longer to apply directly by virtue of the AI Act but are **to be integrated into the MDR and IVDR.**

This integration is to be achieved through delegated and implementing acts (e.g. new Article 5(8) MDR).

Does the AI Act thereby become obsolete for medical devices?

No.

The AI Act remains relevant, in particular for:

- classification as a high-risk system (Article 6)
- market surveillance (Articles 102–109)
- sanctions (Article 112)

What changes is not the substance of the requirements, but their **systemic embedding**.

Practical Implications

This amendment pursues a clear objective: the parallel application of MDR/IVDR and the AI Act is to be reduced and replaced by a more integrated framework.

At the same time, however, a new challenge arises: the requirements become less directly accessible, as they are no longer anchored exclusively in a single regulatory instrument but are distributed across multiple levels.

For manufacturers, this means: regulatory complexity does not decrease, it shifts from the level of **individual requirements to the level of the overall system**.

Regardless of this shift, the role of Notified Bodies remains central. They must continue to demonstrate that they satisfy the specific requirements for the assessment of AI systems, in particular with regard to competencies under the AI Act (e.g. Articles 31 and 43).

5.5 The Digital Omnibus and Deadline Extension

In parallel with the MDR/IVDR Simplification Proposal, the European Commission published the so-called “Digital Omnibus” package in November 2025. This includes, among

other things, amendments to the AI Act, in particular with regard to the implementation deadlines.

The central focus is the postponement of the dates of application for high-risk AI systems under Annex I, which include AI-based medical devices.

Rather than fixed cut-off dates, a graduated approach is now envisaged: the requirements are to apply only once the necessary regulatory prerequisites have been put in place, in particular harmonized standards and guidance documents.

The currently discussed target deadlines shift as follows:

- High-risk AI systems under Annex III: from August 2026 to no later than December 2027
- High-risk AI systems under Annex I (including MDR/IVDR): from August 2027 to no later than August 2028

This adjustment creates additional time for manufacturers, Notified Bodies, and regulatory institutions.

The deadline extension is not a substantive intervention in the requirements of the AI Act. It changes neither their scope nor their direction.

What it changes is the **time pressure.**

And it is precisely here that the risk of misjudgment lies:

The regulatory structures required for implementation, in particular standards, assessment benchmarks, and competencies at Notified Bodies, are still being developed.

For manufacturers, this means: the additional time is not a buffer in the classical sense, but rather a phase in which the key framework conditions are not yet fully defined.

Preparation for the AI Act cannot proceed sequentially, in the sense of "wait first, then implement". It must take place in parallel with the regulatory development.

This applies in particular to:

- building data governance structures
- integrating AI-specific requirements into the QMS and Technical Documentation
- and early coordination with Notified Bodies

The deadline extension shifts the point of application, but not the direction of regulation.

For AI systems in a medical context, this direction is already clearly visible:

The requirements are not diminishing. They are becoming more integrated, more specific, and more closely aligned with actual system behavior.

Those who integrate this trajectory early into their product and quality strategy gain not only time, but above all regulatory stability in an environment that continues to evolve.

6. Roadmap for Manufacturers of AI Medical Devices

The regulatory requirements are complex, but the next steps can be clearly structured. The critical factor is setting the right priorities at an early stage.

The following roadmap distinguishes between short-term measures through to the end of 2026 and medium-term measures through to 2028.

Short-Term (Now to End of 2026)

Step 1: Portfolio analysis and gap analysis

Analyze your entire portfolio systematically:

- Which products use AI?
- Which of these fall under the MDR or IVDR?
- Which require the involvement of a Notified Body?

On this basis, conduct a gap analysis: where do your products currently stand in relation to the requirements of the AI Act and MDCG 2025-6?

Step 2: Targeted QMS extension

An existing ISO 13485-compliant QMS provides the foundation but is not sufficient on its own for AI systems.

Supplement it in a targeted manner with:

- **Data governance processes** (data collection, quality assurance, documentation)
- **MLOps structures** (model training, validation, deployment, monitoring)
- **Change management for AI systems** (clear criteria for substantial modifications, retraining strategies)

Step 3: Extension of the Technical Documentation

The Technical Documentation is the central instrument for demonstrating conformity and must fully reflect the specific characteristics of AI systems.

Supplement it in particular with:

- Description of model architecture and mode of operation
- Structured documentation of training and validation data
- Evidence relating to bias analysis and data representativeness
- Appropriate performance metrics and their justification

Medium-Term (2026–2028)

Step 4: Early engagement of the Notified Body

The assessment of AI systems requires additional competencies on the part of Notified Bodies.

Key questions to clarify:

- Does your Notified Body have the requisite AI Act competency?
- When will this competency be in place?

This coordination is critical for realistic scheduling and market access planning.

Step 5: Active monitoring of standards and norms

The concrete design of the requirements will be substantially shaped by standards.

Particularly relevant are:

- ISO/IEC 42001 (AI management systems)
- ISO/TR 24028 (Trustworthiness in AI)
- IEC 82304-1 (Health software)
- IEC 62304 (Software lifecycle processes)
- as well as planned amendments to existing standards with AI relevance

It is here that the future assessment benchmarks are being established.

Step 6: Continuous monitoring of legislative developments

The regulatory landscape continues to evolve.

Monitor in particular:

- the progress of the MDR/IVDR Simplification Proposal
- the development of the Digital Omnibus
- as well as accompanying guidance documents and delegated acts

The final design may differ significantly from the current proposals in important respects.

7. Conclusion

The regulatory debate surrounding AI in medical technology is frequently understood as an accumulation of new requirements: MDR, IVDR, and now also the AI Act.

This view is too narrow.

What is currently developing is not a parallel coexistence of regulatory frameworks, but an **integrated system** in which requirements overlap, shift, and mutually refine one another.

Three developments are particularly shaping this system:

- The close coupling between classification under the MDR/IVDR and designation as a high-risk AI system
- The progressive integration of AI Act requirements into existing regulatory structures
- The expansion of assessment to encompass additional dimensions such as data quality, system behavior, and cybersecurity

The MDR/IVDR Simplification Proposal reinforces this trajectory. It does not reduce the regulatory substance, it changes its anchoring: less direct parallelism between the frameworks, but deeper integration into the established MedTech framework.

At the same time, the focus of assessment is shifting.

The question is no longer solely whether a system functions, the central question is whether it is transparently understandable **how and under what conditions it functions**.

For AI systems, this is a fundamental difference.

The requirements are not becoming more abstract; they are becoming more concrete:

- Data must be understood and justified.
- System behavior must be observable and explainable.
- Changes must be controlled and placed in a regulatory context.

This trajectory leads to a clear consequence:

Regulatory conformity is no longer a state achieved at a given point in time. It becomes a continuous demonstration across the entire lifecycle of a system.

For manufacturers, this requires a change in perspective.

The focus is shifting:

- from point-in-time approval to ongoing governance
- from documentation to system comprehension
- from isolated requirements to integrated processes

The good news is:

The essential building blocks already exist. Quality management, risk management, and clinical evaluation continue to form the foundation.

The challenge lies in developing these structures in a way that meets the particular demands of data-driven systems.

Ultimately, the decisive question will not be which specific provision of which regulatory framework applies in a given case.

What will matter is whether manufacturers are able to design their systems in such a way that, under real-world conditions, they remain transparent, controllable, and reliable.

That is the measure by which regulatory quality will be judged in the future.

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9. About Entourage

Entourage is a specialist consulting firm for the life sciences industry, supporting pharmaceutical, biotech, medical device, and in-vitro diagnostic (IVD) manufacturers across the full product lifecycle. The firm's capabilities span regulatory strategy and submissions, quality management and compliance, market access, health economics, and supply and technical operations – covering both drug development and device approval pathways across EU and international frameworks including EMA, FDA, MDR, IVDR, and ISO 13485. With a senior team of regulatory affairs, quality, and market access professionals, Entourage combines strategic advisory with hands-on operational delivery: from IND/CTA readiness and HTA dossiers to conformity assessment, FMEA, and post-market surveillance. The firm serves clients across Europe and beyond, operating where specialist expertise and execution capacity are needed most.

10. About the Author

Diana Hohage is a Senior Regulatory Affairs and Quality Management professional with 30 years of experience in the life sciences industry, including more than 15 years specializing in medical technology and over 8 years in consulting. She advises medical device and IVD manufacturers on regulatory strategy, technical documentation, and risk management under MDR, IVDR, and ISO 13485, and holds certifications as Lead Auditor for ISO 13485 and MDSAP. A co-author of *Praxis Medizinprodukterecht* and a regular speaker at industry conferences including TÜV Rheinland and Sustainamed, she brings both strategic depth and hands-on expertise to complex regulatory challenges.

