



2026 comes with BIG CHANGES

What changes - Big picture

Before	After
Regulatory work could be managed on an ad hoc basis	Regulatory work must function continuously
Focus on passing an audit	Focus on being audit-ready at all times
Documentation is updated sporadically	Documentation must be kept continuously up to date
Manual work could be sufficient	Manual work quickly becomes unsustainable

MDR artikel 10, Annex II–III • IVDR artikel 10, Annex II–III • ISO 13485:2016 §4.1, §7.5

What drives the change - Big picture

MDR and IVDR require manufacturers to **maintain regulatory compliance continuously** and to **remain aware of applicable legal and guidance updates** throughout the product lifecycle (Articles 10, Annex I, Annex III)

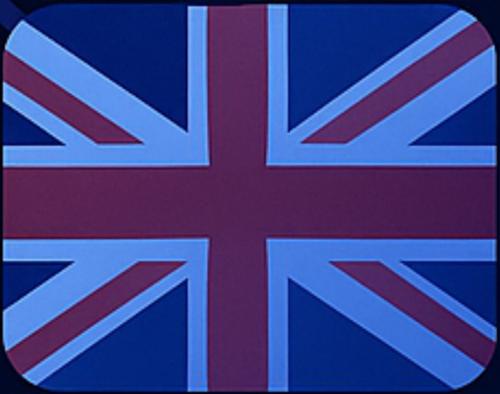
By **2026**, transition tolerance has ended.
Regulators now expect **up-to-date applicable requirements**, not retrospective reviews.

Managing regulatory updates is no longer episodic.
It is a continuous compliance function.

MDR artikel 10, Annex II–III • IVDR artikel 10, Annex II–III • ISO 13485:2016 §4.1, §7.5

A system failure without a remedy



- > Different rules for every market
- > New and revised demands, all the time
- > No one can keep this up to date automatically

A system failure with severe consequences

Fines and additional workload

Delayed product launches

Market withdrawals or recalls



hoodin ▶▶
COMPLIANCE STUDIO

Ask Compliance Assistant

Ask a regulatory question...

STUDIO AGENT

Your Profiles

Medical Device X
0 LISTS

+ Add Product Profile

+ Add Company Profile
0 LISTS

ADD PRODUCT AND COMPANY PROFILES

AI Agents

Regulations
Expert

Guidance
Expert

Standards
Expert

EXPERT AGENTS

Build Lists

Set up an Applicable List

Generate a harmonized list of regulatory requirements for your product.

AUTOMATED APPLICABLE LISTS

OmniPod DASH

Europe / EU

Edit

Remove Product



AI generated suggestions for your list 3

Using your product data and scope, Hoodins AI can generate list entries, what regulations/directive that should be added, what app

TAILORED RATIONAL AND SECTIONS OF REGULATIONS

Regulation/Directive

Rationale for applicability

Directive 2014/53/EU, Radio Equipment Directive (RED)

Directive 2014/53/EU (Radio Equipment Directive) governs radio equipment placed on the EU market that intentionally emits or receives radio waves for communication or radiodetermination purposes. The device description confirms the presence of radio frequency/wireless technology and that it is subject to trade into and out of the EU and requires CE marking. These characteristics bring the product into scope of Article 1 of Directive 2014/53/EU, triggering the need to meet its essential requirements for health and safety, electromagnetic compatibility, and efficient use of the radio spectrum.

+ ADD TO LIST

- DISMISS

Ask AI

Edit Row

ACCESS REGULATIONS AGENT TO INITIATE A DIALOGUE ABOUT THE ACTUAL REGULATION

Directive 2011/65/EU, RoHS Directive

The device is electrical and electronic equipment because it contains a battery and incorporates radio frequency/wireless technology. It is placed on the EU market and requires CE marking. Directive 2011/65/EU (RoHS) therefore governs the restriction of certain hazardous substances in its homogeneous materials. Even though no harmful or persistent chemicals are identified in the product attributes, RoHS still governs the design and material composition of all electrical and electronic equipment within its scope, including medical devices, to ensure restricted substances remain below the permitted thresholds.

+ ADD TO LIST

- DISMISS

Ask AI

Edit Row

SUGGESTIONS ON APPLICABLE REGULATIONS

EXPORT AS CSV (EXCEL)

ALL CHATS
STORED

The screenshot shows a chat application interface. On the left is a sidebar titled "Agents" with a "+" icon, listing four agents: "Studio Assistant" (23), "Regulations Agent" (11), "Guidance Agent" (7), and "Standards Agent" (45). The main chat window is titled "Regulations Agent" and shows "Online" status. The chat history includes three messages: a user question about the EU AI Act's impact on medical device software, an AI response explaining its applicability under MDR, and a user follow-up question about compliance requirements. The AI response provides a list of five steps to remain compliant and offers to generate a validation checklist. At the bottom is a text input field with the placeholder "Ask a question..." and a send button.

< Agents + Regulations Agent
Online

☆ Studio Assistant 23

📖 Regulations Agent 11

↗ Guidance Agent 7

☆ Standards Agent 45

The EU AI Act was just adopted. Does this impact medical device software already on the market?
14:09:02

📖 Yes. The AI Act is indirectly applicable to medical device software under MDR. It introduces additional horizontal compliance obligations for high-risk AI used as part of a medical device. The impact is primarily on risk management, data governance, post-market monitoring, and technical documentation alignment with MDR Annex II and III.
14:10:02

What do we need to do to remain compliant?
14:14:02

📖 To remain compliant, you should:

- Confirm whether any software functions meet the AI Act definition of high-risk AI.
- Update the risk management file to include AI-specific hazards and controls.
- Verify dataset governance and bias controls used for training and validation.
- Align post-market surveillance procedures with AI Act monitoring obligations.
- Prepare AI-specific technical documentation in parallel with MDR Annex II.

If you want, I can generate a validation checklist mapped to MDR Annex II and the AI Act for audit use.
14:15:02

Ask a question...

THE AI IS TRAINED ON
YOUR PRODUCT AND
GLOAL REGULATIONS

Regulatory Updates

Review regulatory changes relevant to your products and markets. Filter and analyze updates by impact level and use AI for detailed impact analysis. Free for: » »

GET ALL UPDATES ON APPLICABLE REGULATIONS

Filters

Markets ▾

Regulation Type ▾

Regulations ▾

Authorities ▾

All ▾

Tags

General Has Impact >

Date ▾

29 Apr 2024 📅

To ▾

29 Apr 2024 📅

Regulatory Updates

Emerging Regulatory Framework for Medical Device Software in the US General

FDA : 29 April 2024

The FDA released a guidance introducing new rules concerning SaMD (Software as a Medical Device). The framework primarily focuses on clinical evaluation, risk management, and cybersecurity for SaMD.

View Details

AI Impact Analysis

Ask AI

Ask AI

IVDR Annex I Amendments Published Has Impact

Europe : 28 April 2024

The European Commission has revised Annex I of the IVDR. The amendments emphasize updated requirements for performance evaluation, labelling, and post-market surveillance.

View Details

AI Impact Analysis

Ask AI

Ask AI

Updates to ISO 14971 Risk Management Standard General

International Organization for Standardization

ISO 14971:2024 introduces notable changes in the risk management process and cybersecurity considerations for medical devices.

AI Impact Analysis ×

Applicability

OmmPod DASH

Affected Areas

Performance Evaluation

Labelling

Post-Market Surveillance

Risk Level

High

Suggested Actions

- Update performance evaluation processes.
- Strengthen PMS procedures to meet revised post-market requirements.

Ask AI about this change

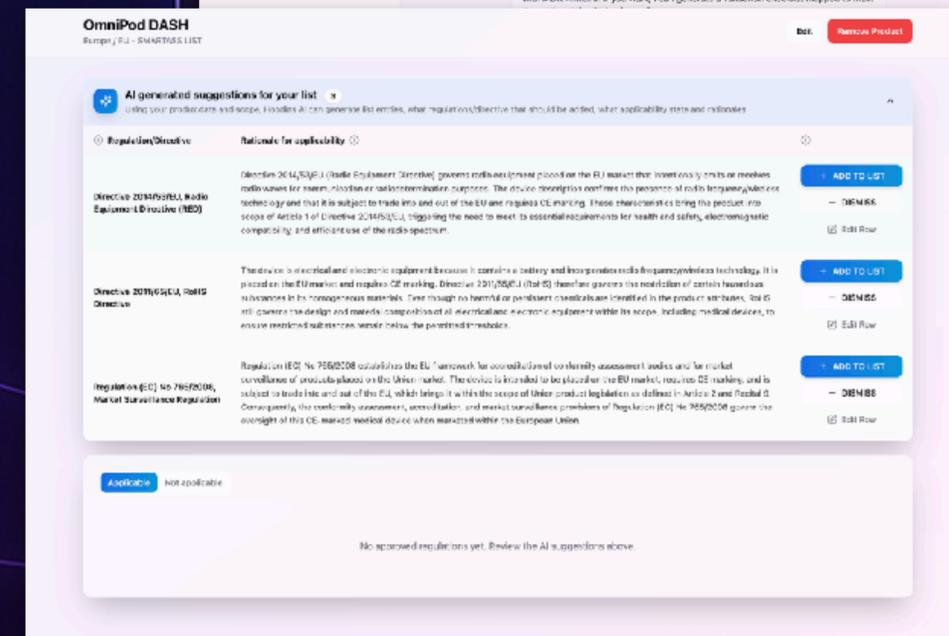
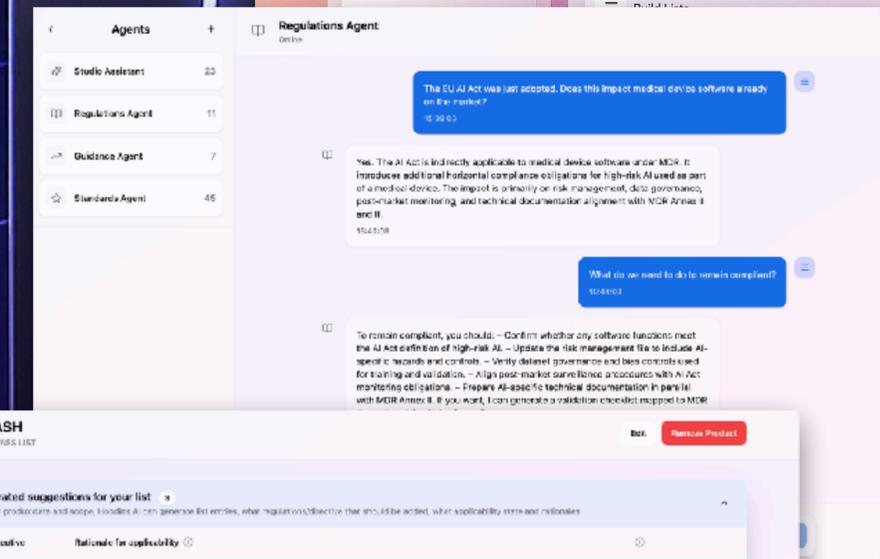
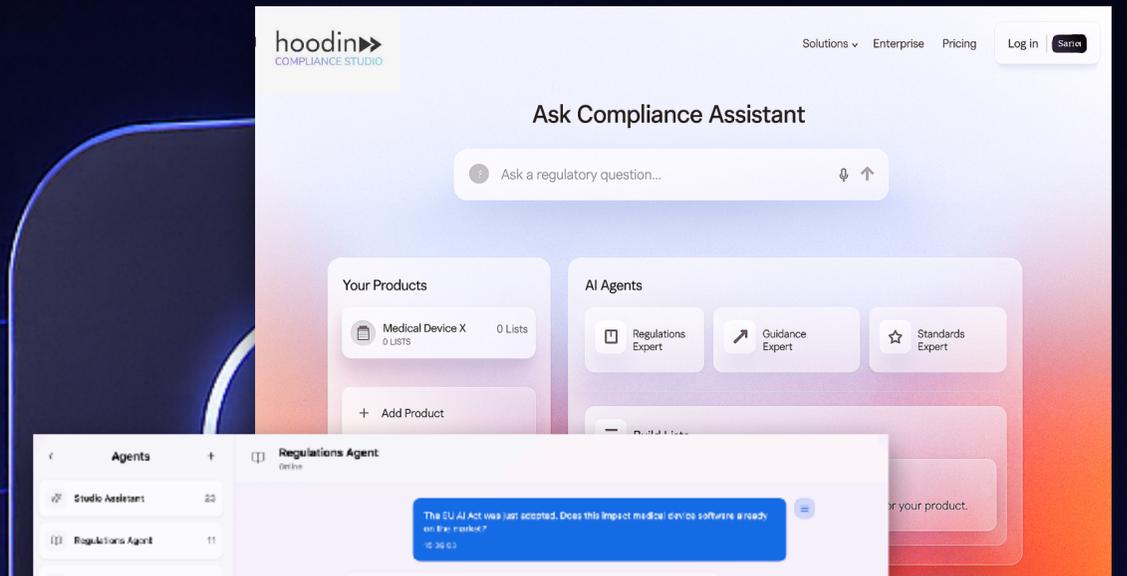
THE REGULATIONS AGENT WILL ASSESS EACH UPDATE AND SUGGEST ACTIONS

Hoodin Compliance Studio supports both your applicable requirements management and your day-to-day regulatory change control

Receive answers and support from trained AI regulatory experts to manage daily compliance challenges.

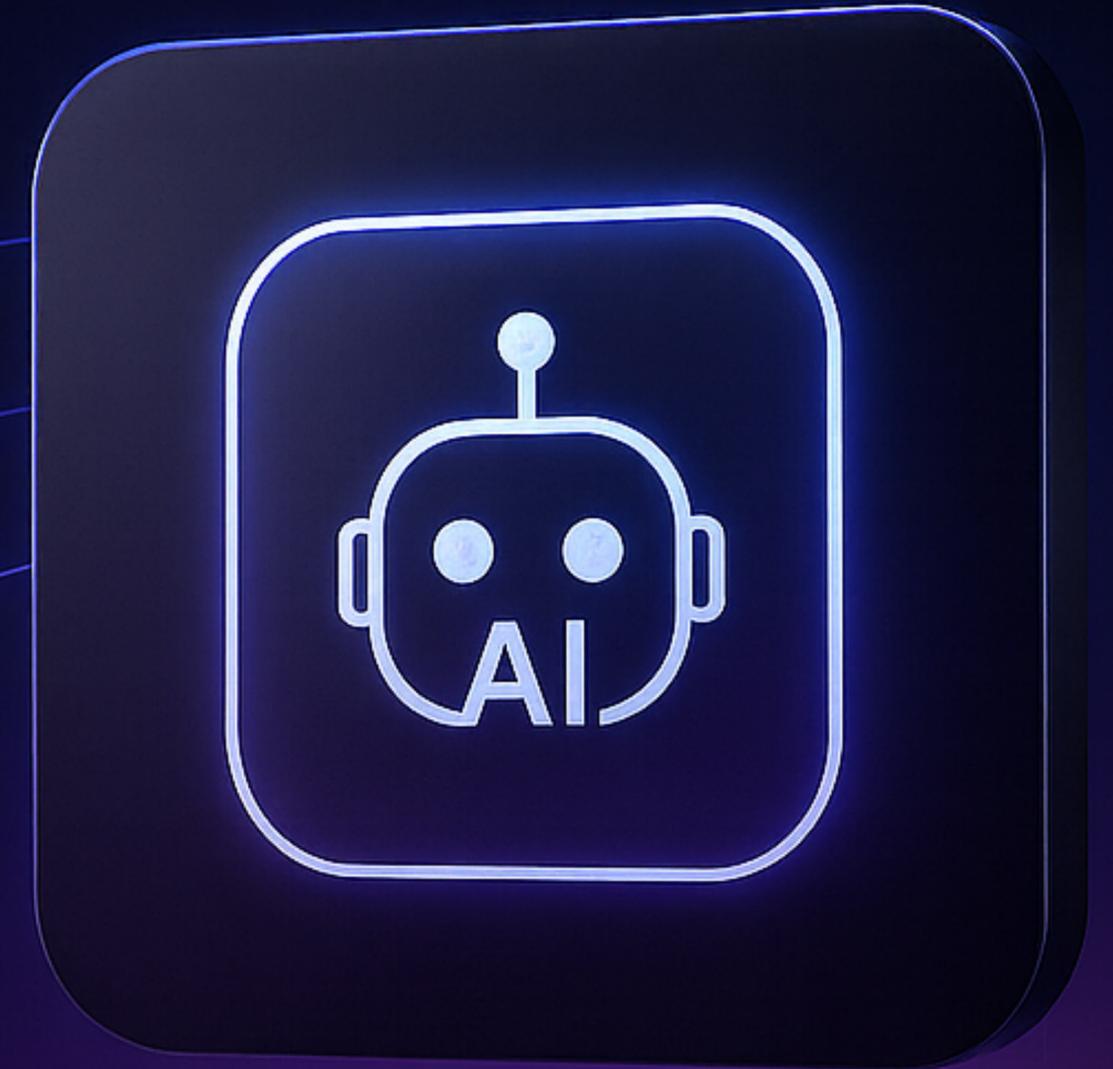
Add products and essential metadata to further refine the AI experts' understanding.

Establish Applicable Lists for all Regulations, Guidances, and Standards relevant to your product. Automatically receive all updates, along with AI expert interpretation of what they mean for your specific product.



WHY NOT USE GENERAL AI MODELS

- ChatGPT, Gemini, Copilot and similar tools are not validated for use in life sciences.
In many cases, they are not permitted for regulatory work.
- They are general-purpose chatbots and lack the structured, controlled environment required for compliant regulatory use.



QUESTIONS?



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<https://www.hoodin.com/compliance-studio-signup>

hoodin▶▶ Smart Compliance List Company ▼ Pricing Partners Resources ▼ 14-day Free Trial Login

Want early access to Hoodin's next RA/QA release?

We're preparing a small early-access group for our upcoming RA/QA agent. If you want early insights, direct product updates, and the chance to influence how the tool develops, you're welcome to sign up.

Join if you'd like to:

- receive updates on the next release
- get invited to early testing
- share feedback on how the tool supports real RA/QA workflows

Fill in the form and we'll get in touch!

Get updates about the Compliance Studio

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Enter your last name

Email *
Enter your email

Position
Enter a position or job title

Company name
Company name