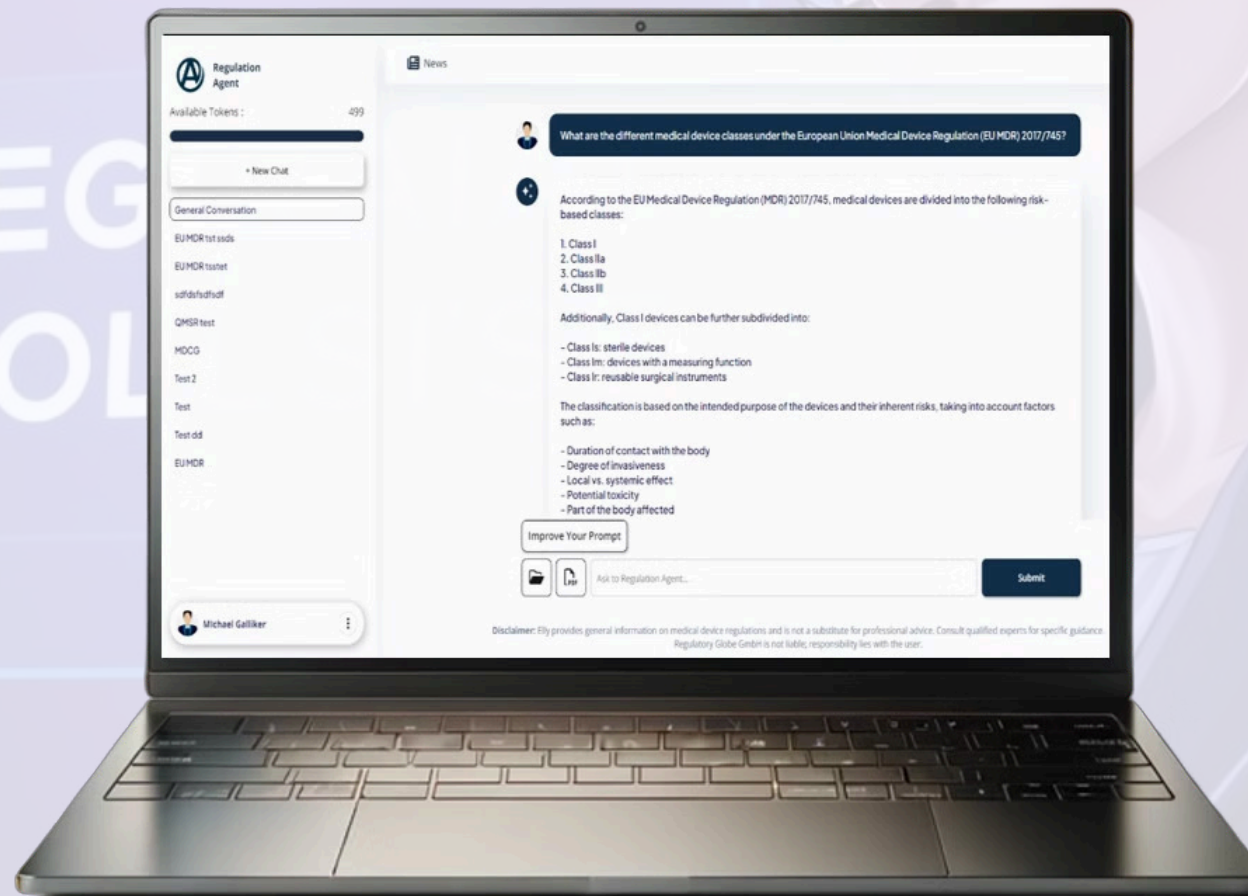


# Elly - Global Regulatory Know-How at Your Fingertips

AI powered technology that creates initial regulatory assessments in seconds



Free Trial

# Who is Elly?

## AI-Powered

Elly a is a medical device and In-vitro diagnostic trained Regulatory Affairs Assistant built on advanced AI technology.

## Global Expertise

Elly provides insights and clarity on laws, regulations and guidances globally.

## Simple Interface

Elly provides a simple interface for Regulatory Affairs Professionals to understand complex regulatory documentation faster and better.

# Problems

## 1 Research

Staying updated on the latest changes in regulatory landscape is a time-consuming and resource-intensive process.

## 3 Document Size

Extracting relevant information from extensive documents by reading can be very time-consuming.

## 2 Complexity




















Regulations are usually written in a convoluted way, it often requires laborious scrolling back and forth until you understand the context.

## 4 Language Barriers

Sometimes Regulations and Guidances are written in a language nobody can understand in the Company.

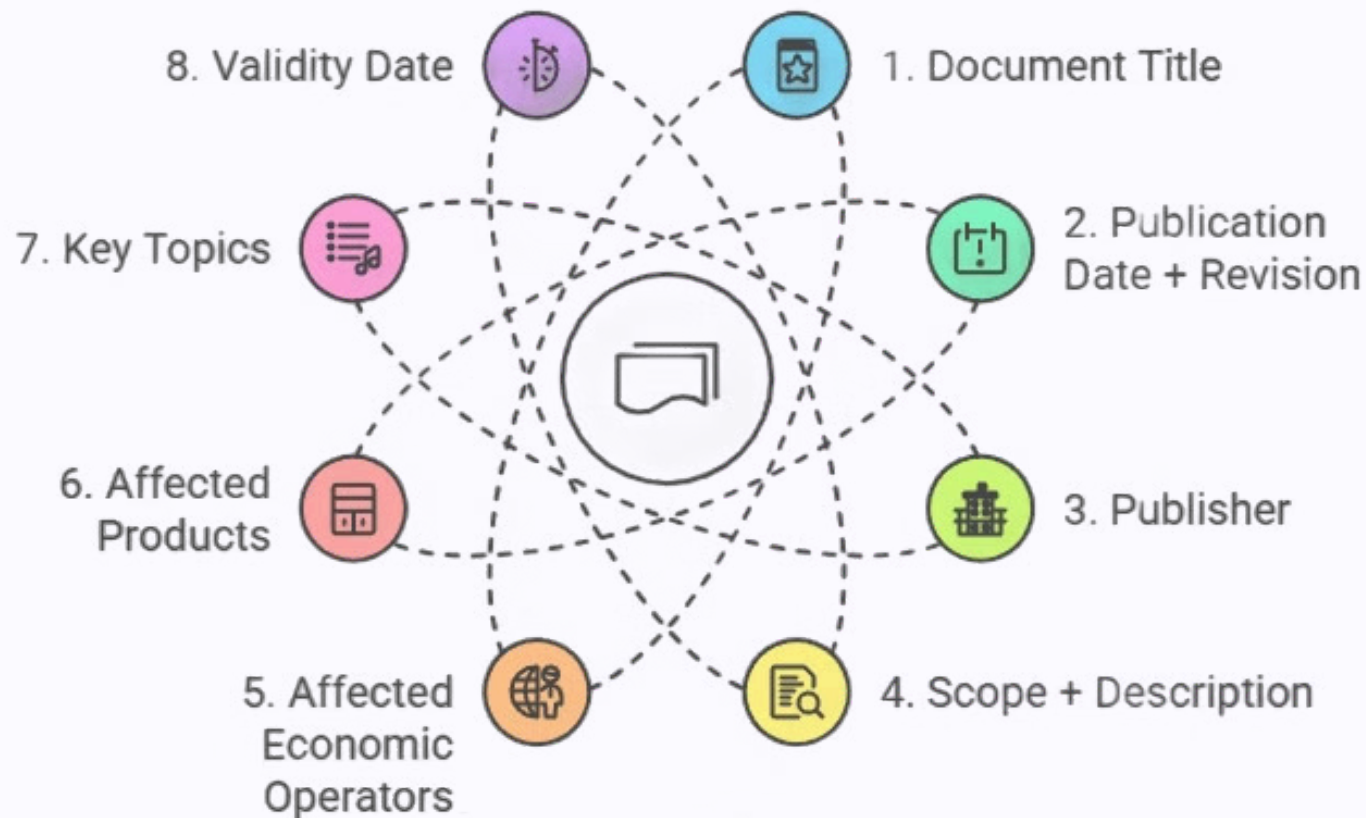
# Solution - Research Elimination

Elly eliminates the need for time-consuming research. All relevant changes to **regulations**, **guidelines** and **standards** in the medical and in-vitro diagnostic field are listed under “News”.

News			
<input type="text" value="Search..."/>			
Document name	Country	Publication date	
 Guidance on the regulation of In Vitro Diagnostic medical devices in Great Britain.pdf	UK	Jan 15, 2025	 Ask document
 The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024_ guidance on implementation.pdf	UK	Jan 15, 2025	 Ask document
 Premarket Approval Application and Humanitarian Device Exemption Modular Review.pdf	USA	Jan 13, 2025	 Ask document
 MDCG 2024-7 Rev.1 Preliminary assessment review template - MDR (Regulation (EU) 2017_745).pdf	EU	Jan 10, 2025	 Ask document
 NB_2265 3EC International as EU MDR.pdf	EU	Jan 8, 2025	 Ask document
 MDCG 2023-3 Rev 2_Q&A vigilance terms and concepts.pdf	EU	Jan 7, 2025	 Ask document
 Regulation of devices in Northern Ireland.pdf	UK	Jan 7, 2025	 Ask document
 Guidance 5061 Shortages.pdf	USA	Jan 7, 2025	 Ask document
Rows per page: 10  1 - 10 of 4090  1 			

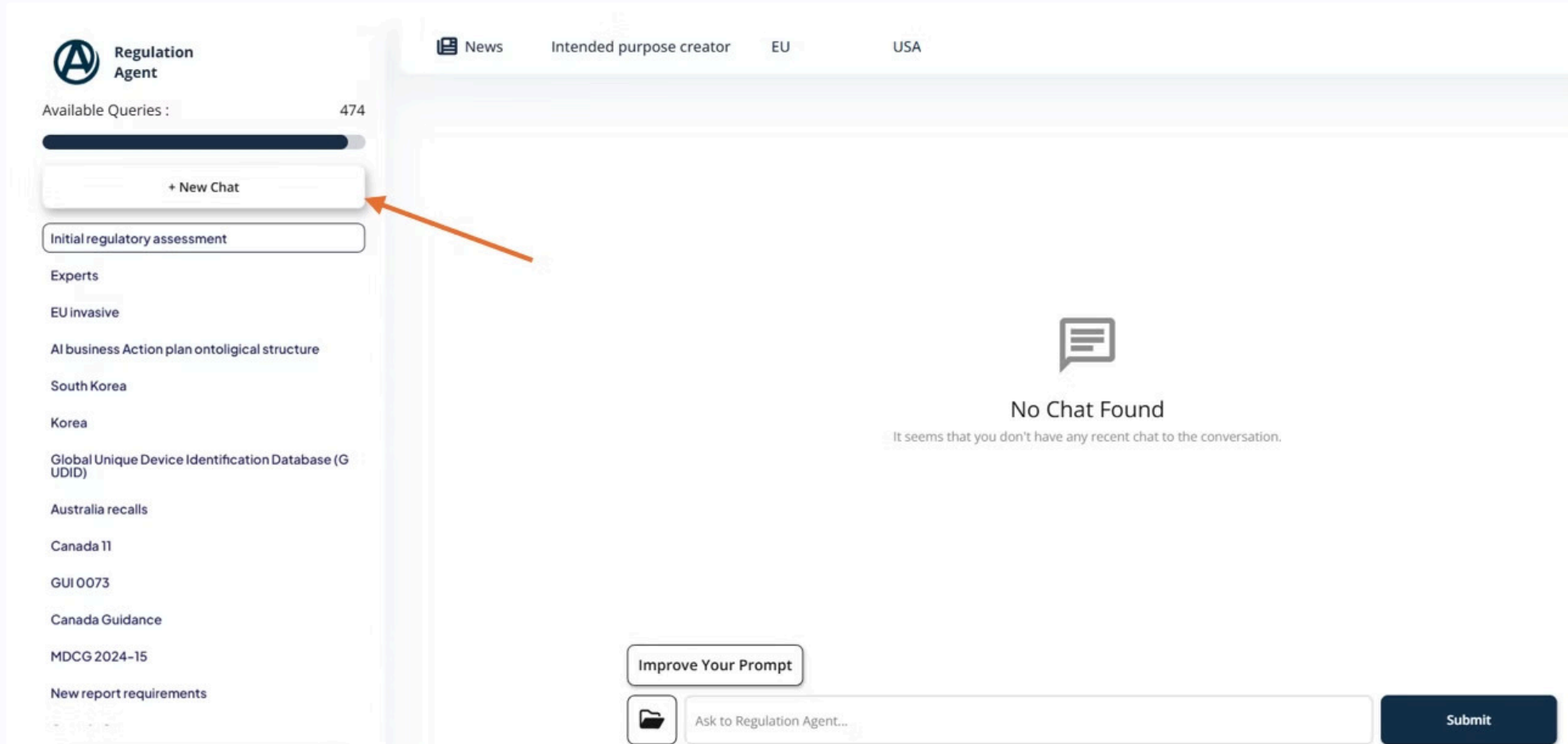
# Solution - Initial Regulatory Assessment

It does not matter in which language, how large or complex the regulation is. Simply click on the "**Summarize Document**" button and Elly will start creating an Initial regulatory assessment in the following structured way:



# How it works

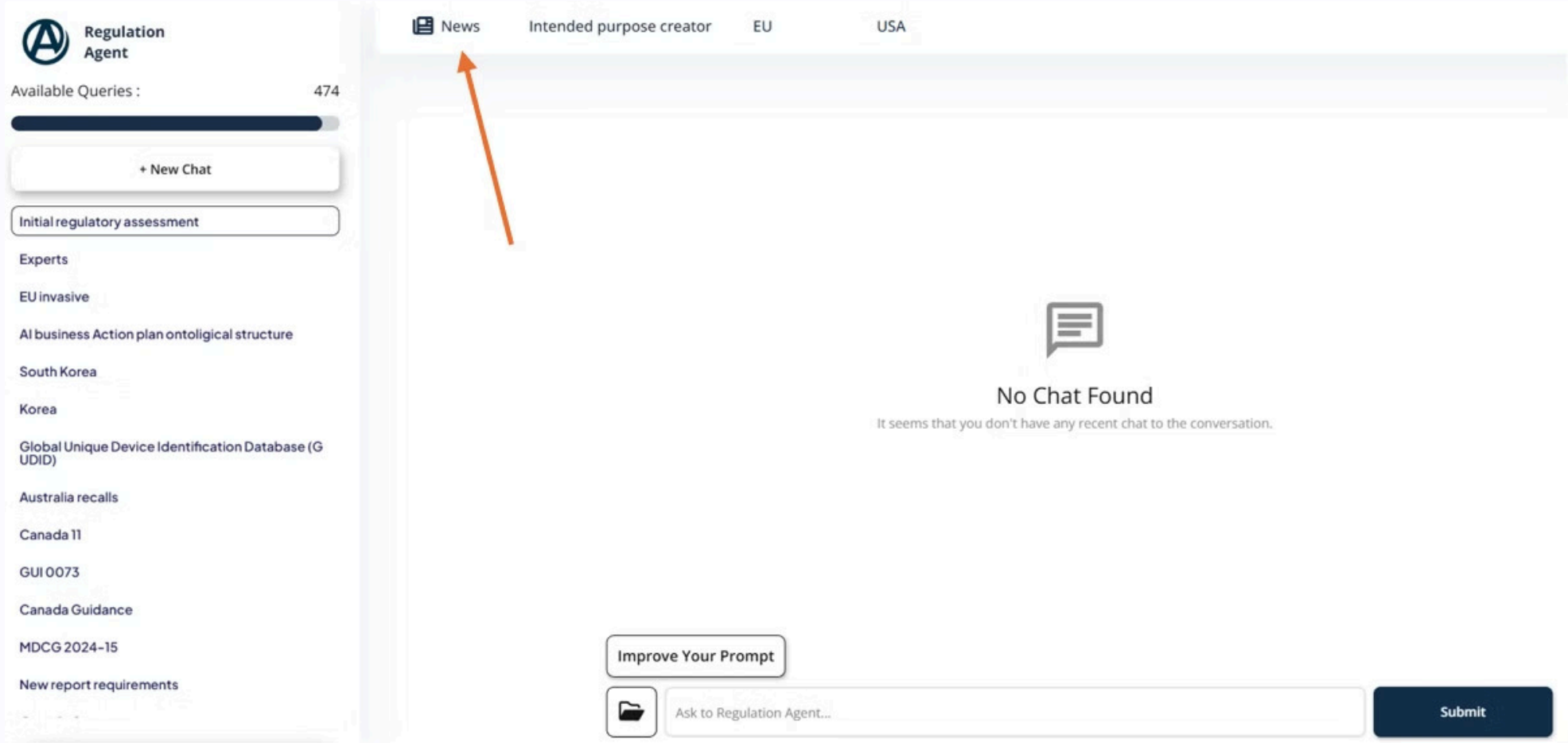
## Step 1 - Create a new chat:



The screenshot displays the 'Regulation Agent' web interface. On the left sidebar, the 'Regulation Agent' logo is at the top, followed by 'Available Queries : 474' and a progress bar. Below this is a '+ New Chat' button, which is highlighted by an orange arrow. Underneath the button is a list of queries: 'Initial regulatory assessment', 'Experts', 'EU invasive', 'AI business Action plan ontological structure', 'South Korea', 'Korea', 'Global Unique Device Identification Database (GUDID)', 'Australia recalls', 'Canada 11', 'GUI 0073', 'Canada Guidance', 'MDCG 2024-15', and 'New report requirements'. The main content area on the right shows a 'No Chat Found' message with a speech bubble icon and the text 'It seems that you don't have any recent chat to the conversation.' At the bottom of the interface, there is a section titled 'Improve Your Prompt' with a folder icon and a text input field labeled 'Ask to Regulation Agent...'. To the right of this input field is a dark blue 'Submit' button.

# How it works

Step 2 - Go to "News":



The screenshot displays the 'Regulation Agent' web interface. On the left sidebar, the 'Regulation Agent' logo is at the top, followed by 'Available Queries : 474' and a progress bar. Below this is a '+ New Chat' button and a list of queries including 'Initial regulatory assessment', 'Experts', 'EU invasive', 'AI business Action plan ontological structure', 'South Korea', 'Korea', 'Global Unique Device Identification Database (GUDID)', 'Australia recalls', 'Canada 11', 'GUI 0073', 'Canada Guidance', 'MDCG 2024-15', and 'New report requirements'. The main content area has a top navigation bar with tabs: 'News' (selected, indicated by an orange arrow), 'Intended purpose creator', 'EU', and 'USA'. The main area shows a 'No Chat Found' message with a speech bubble icon and the text 'It seems that you don't have any recent chat to the conversation.' At the bottom, there is an 'Improve Your Prompt' button, a text input field with a folder icon and placeholder text 'Ask to Regulation Agent...', and a 'Submit' button.

Regulation Agent

Available Queries : 474

+ New Chat

Initial regulatory assessment

Experts

EU invasive

AI business Action plan ontological structure

South Korea

Korea

Global Unique Device Identification Database (GUDID)

Australia recalls

Canada 11

GUI 0073

Canada Guidance

MDCG 2024-15

New report requirements

News Intended purpose creator EU USA

No Chat Found

It seems that you don't have any recent chat to the conversation.

Improve Your Prompt

Ask to Regulation Agent...

Submit



# How it works

## Step 3 - Ask document of your choice:

The screenshot displays a web application interface with a top navigation bar containing 'News', 'Intended purpose creator', 'EU', and 'USA'. The 'News' tab is active, showing a list of documents. A search bar is located in the top right corner of the list area. The document list has columns for 'Document name', 'Country', and 'Publication date'. Each row includes a PDF icon, the document name, the country, the publication date, and an 'Ask document' button. An orange arrow points to the 'Ask document' button for the document 'MDCG 2023-3 Rev 2\_Q&A vigilance terms and concepts.pdf'. The bottom of the interface shows pagination controls: 'Rows per page: 10' and '1 - 10 of 4087'.

Document name	Country	Publication date	Action
MDCG 2024-7 Rev.1 Preliminary assessment review template - MDR (Regulation (EU) 2017_745).pdf	EU	Jan 10, 2025	Ask document
NB_2265 3EC International as EU MDR.pdf	EU	Jan 8, 2025	Ask document
MDCG 2023-3 Rev 2_Q&A vigilance terms and concepts.pdf	EU	Jan 7, 2025	Ask document
Regulation of devices in Northern Ireland.pdf	UK	Jan 7, 2025	Ask document
Guidance-506j-Shortages.pdf	USA	Jan 7, 2025	Ask document
The Saudi National Diagnostic Reference Levles (NDRLs) Version 3.0.pdf	Saudi Arabia	Jan 6, 2025	Ask document
MD final classification list merged.pdf	India	Jan 2, 2025	Ask document
MUI600 00 016a MR Obligations Economic Operators Version 6.pdf	Switzerland	Jan 1, 2025	Ask document

Rows per page: 10 1 - 10 of 4087



# How it works

Final: Step 4 - Click on "Summarize Document":

The screenshot displays the Regulation Agent interface. On the left, a sidebar lists various queries and documents, including "Initial regulatory assessment", "Experts", "EU invasive", "AI business Action plan ontological structure", "South Korea", "Korea", "Global Unique Device Identification Database (GUDID)", "Australia recalls", "Canada 11", "GUI 0073", "Canada Guidance", "MDCG 2024-15", and "New report requirements". The main area shows a summary report for the document "MDCG 2023-3 Rev 2\_Q&A vigilance terms and concepts.pdf". The report includes five sections: 1. Title of document, 2. Publication or issued date and revision of the document, 3. Name of the agency, government, or company who have published the document, 4. Scope and short description of the document, and 5. Which economic operator(s) will be affected by this document. An orange arrow points to the "Summarize Document" button at the bottom of the report. The interface also features a "Submit" button and a "Ask to Regulation Agent..." input field.

Regulation Agent

Available Queries : 473

+ New Chat

Initial regulatory assessment

Experts

EU invasive

AI business Action plan ontological structure

South Korea

Korea

Global Unique Device Identification Database (GUDID)

Australia recalls

Canada 11

GUI 0073

Canada Guidance

MDCG 2024-15

New report requirements

News Intended purpose creator EU USA

Based on the provided context, I'll create a summary report for the document "MDCG 2023-3 Rev 2\_Q&A vigilance terms and concepts.pdf" as requested:

1. Title of document:  
MDCG 2023-3 Rev. 2 - Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746
2. Publication or issued date and revision of the document:  
- Publication date: January 2025  
- Revision: Rev. 2 (Second revision)
3. Name of the agency, government, or company who have published the document:  
Medical Device Coordination Group (MDCG)
4. Scope and short description of the document:  
This document aims to clarify important terms and concepts outlined in Section 2 of Chapter VII of Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). It provides guidance on the implementation of vigilance requirements under these Regulations.
5. Which economic operator(s) will be affected by this document:  
- Manufacturers  
- Importers  
- Distributors  
- Authorized Representatives

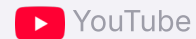
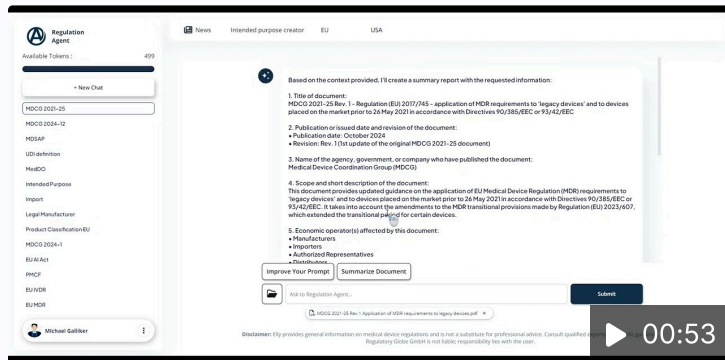
Improve Your Prompt Summarize Document

Ask to Regulation Agent...

Submit

MDCG 2023-3 Rev 2\_Q&A vigilance terms and concepts.pdf x

# Video - How it works



## Initial Regulatory Assessment with One Click

With the document summarizer, you are able to create an initial regulatory assessment of any document.

Watch

# Advantages



Structured Initial Regulatory Assessment in  
Seconds



Transparent Sources



No Language Barriers



Always Up to Date

# Contact Information

## Regulatory Globe GmbH

Michael Galliker  
Founder and CEO

Tel.: +41 79 476 43 19

E-Mail: [info@regulatoryglobe.com](mailto:info@regulatoryglobe.com)

Webpage Elly: [www.regulationagent.com](http://www.regulationagent.com)

