Basic information

2024/0021(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices Amending Regulation 2017/745 2012/0266(COD) Amending Regulation 2017/746 2012/0267(COD) **Subject** 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.11 Precision engineering, optics, photography, medical 4.20.05 Health legislation and policy 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety		

Committee for opinion	Rapporteur for opinion	Appointed
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

European Committee of the Regions

Key events

Date	Event	Reference	Summary
23/01/2024	Legislative proposal published	COM(2024)0043	Summary
26/02/2024	Committee referral announced in Parliament, 1st reading		
25/04/2024	Decision by Parliament, 1st reading	T9-0368/2024	Summary

30/05/2024	Act adopted by Council after Parliament's 1st reading		
13/06/2024	Final act signed		
09/07/2024	Final act published in Official Journal		

Technical information

Procedure reference	2024/0021(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Nature of procedure	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/745 2012/0266(COD) Amending Regulation 2017/746 2012/0267(COD)
Legal basis	Rules of Procedure EP 170 Treaty on the Functioning of the EU TFEU 168-p4 Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/14040

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0368/2024	25/04/2024	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00054/2024/LEX	13/06/2024	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2024)0043	23/01/2024	Summary

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2024)0043	09/04/2024	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
	Economic and Social Committee:			

ESC	opinion, report	CES0746/2024	20/03/2024	

Additional information		
Source	**Document**	**Date**
EP Research Service	Briefing	03/04/2024

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Name	Role	Committee	Date	Interest representatives
WÖLKEN Tiemo	Shadow rapporteur	ENVI	22/02/2024	Medical Mountains
WÖLKEN Tiemo	Shadow rapporteur	ENVI	29/01/2024	MedTech Europe

Other Members

Name	Date	Interest representatives
LIESE Peter	18/03/2024	Bundesverband Medizintechnologie
LIESE Peter	04/03/2024	Bundesverband Medizintechnologie
NIEBLER Angelika	22/02/2024	Deutsche Sozialversicherung Europavertretung

Final act	
Regulation 2024/1860 OJ OJ L 09.07.2024	Summary

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices

2024/0021(COD) - 09/07/2024 - Final act

PURPOSE: to address risks of shortages of in vitro diagnostic medical devices in the Union and ensure the gradual roll-out of the European database on medical devices (EUDAMED).

LEGISLATIVE ACT: Regulation (EU) 2024/1860 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

CONTENT: the regulation updates law on medical devices in order to help **prevent shortages of in vitro diagnostic medical devices** (IVDs) in the EU and to facilitate the timely deployment of Eudamed.

In order to guarantee the availability of in vitro diagnostics, the regulation **extends the deadline for transitioning** to the new system under certain conditions, to avoid shortages of critical IVDs without compromising on safety.

The changes extend the transitional periods that are applicable to 'legacy devices', i.e., those covered by a certificate or declaration of conformity. The additional time granted to companies depends on the type of device:

- high individual and public health risk devices such as HIV or hepatitis tests (class D) would have a transition period until **December 2027**;

- high individual and/or moderate public health risk devices such as cancer tests (class C), would have a transition period until **December 2028**;

- lower risk devices (class B such as pregnancy tests and class A sterile devices such as blood collection tubes), have a transition period until **December 2029**.

The new regulation also enables a **gradual roll-out of the European database on medical devices (EUDAMED)** by requiring manufacturers to provide information about their products to existing EUDAMED modules without needing to wait for the remaining modules to be completed. This mandatory registration is expected to take effect as of late 2025.

The revision also introduces an **obligation for manufacturers** to give prior notice about any interruption of supply of certain critical medical devices or IVDs to relevant authorities, health institutions, healthcare professionals and economic operators to whom they supply the device.

ENTRY INTO FORCE: 9.7.2024.

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices

2024/0021(COD) - 23/01/2024 - Legislative proposal

PURPOSE: to address risks of shortages of in vitro diagnostic medical devices in the Union and ensure the timely roll-out of Eudamed.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2017/745 (Medical Devices Regulation (MDR)) and Regulation (EU) 2017/746 (In Vitro Diagnostic Medical Devices Regulation (IVDR)) of the European Parliament and of the Council set a strengthened regulatory framework for medical devices and in vitro diagnostic medical devices (IVDs).

The MDR has been applied since 26 May 2021. A transitional period has been extended by Regulation (EU) 2023/607 and will end on either 31 December 2027 or 31 December 2028, depending on the device's risk class and subject to certain conditions.

The IVDR has applied since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transitional period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower-risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

CONTENT: this Commission proposal aims to ensure availability of safe devices, essential for healthcare systems, and protect patient care. The latest available data shows that a high number of IVDs currently on the market has not factored in the new rules (nor has been replaced by other devices), meaning that those devices would no longer be available. The number of devices which have not factored in the new rules and are **not expected to transition in time** is particularly high for high risk IVDs (class D). These include important tests detecting infections in the context of blood transfusions or organ donations.

Therefore, this proposal for targeted amendments addresses **two urgent issues**.

Ensuring the availability of in vitro diagnostics

The proposal aims to further **extend the transitional periods to give manufacturers and notified bodies more time to complete the necessary conformity assessment procedures for certain IVDs** to mitigate the risk of shortages of these products, especially of high-risk IVDs, which are used, for example, to test for infections in blood or organ donations or for blood grouping for transfusions. This extension will be subject to conditions and therefore safeguard the high level of requirements set out by the legislation and protect public health.

The changes extend the transitional periods that are applicable to 'legacy devices', i.e., those covered by a certificate or declaration of conformity. The additional time granted to companies depends on the type of device:

- high individual and public health risk devices such as HIV or hepatitis tests (class D) would have a transition period until December 2027;

- high individual and/or moderate public health risk devices such as cancer tests (class C), would have a transition period until December 2028;

- lower risk devices (class B such as pregnancy tests and class A sterile devices such as blood collection tubes), have a transition period until December 2029.

The proposal also introduces a requirement for manufacturers to **give prior notice** to authorities, as well as to distributors or health institutions, **if they foresee the interruption of supply of IVDs or medical devices**, which would pose risks to patient care. This measure would enable healthcare systems to have more time to take action to safeguard patient care.

More transparency on medical devices

The mandatory use of the European database on medical devices, Eudamed, is key for the effective and efficient implementation of the Medical Device and IVD Regulations. It will increase transparency in the EU, providing an overview of all medical devices available on the European market. The proposal to enable and **accelerate a gradual roll-out of Eudamed** and notably **s**peed up the launch of the parts of Eudamed that are already finalised, so that it is mandatory earlier (as from late 2025).

Lastly, this draft Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of in vitro diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the last electronic system of

Eudamed. To attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should **enter into force as a matter of urgency**.

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain in vitro diagnostic medical devices

2024/0021(COD) - 25/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 511 votes to 20, with 21 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic (IVD) medical devices.

The European Parliament adopted its position at first reading under the ordinary legislative procedure, taking over the Commission's proposal.

The proposed regulation aims to alleviate the risk of shortages of in vitro diagnostic medical devices in the EU and to facilitate the timely deployment of Eudamed.

With a view to ensuring the availability of in vitro diagnostics, the proposal aims to further extend the transitional periods to give manufacturers and notified bodies more time to complete the necessary conformity assessment procedures for certain IVDs to mitigate the risk of shortages of these products, especially of high-risk IVDs, which are used, for example, to test for infections in blood or organ donations or for blood grouping for transfusions. This extension will be subject to conditions and therefore safeguard the high level of requirements set out by the legislation and protect public health.

Secondly, the proposal aims to allow a gradual roll-out of the electronic systems integrated into the European database on medical devices (Eudamed) that have already been completed, instead of waiting for the completion of the last of the six modules for the mandatory use of Eudamed. The use of Eudamed, and in particular its systems for registering economic operators, devices and certificates, should improve transparency and provide information on devices present on the EU market, thus helping to monitor device availability.

Lastly, the proposal aims to impose an obligation on manufacturers to give notice before discontinuing the supply of certain critical medical devices and IVDs.

This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of in vitro diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the electronic system on clinical investigations and performance studies of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure the availability of such devices the certificates of which have already expired or are due to expire before 26 May 2025, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the Official Journal of the European Union.