Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2020/0060(COD)
Medical devices Amending Regulation 2017/745 2012/0266(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 Legislative priorities The EU?s response to the Covid-19 pandemic	Procedure completed

Key players

	Committee responsible	Rapporteur	Appointed
European Parliament	ENVI Environment, Public Health and Food Safety		
Council of the European Union			
European Economic and Social Committee			
European Committee of the Regions			

Key events

03/04/2020	Legislative proposal published	COM(2020)0144	Summary
14/04/2020	Decision by committee, without report		
16/04/2020	Committee referral announced in Parliament, 1st reading		
17/04/2020	Decision by Parliament, 1st reading	T9-0053/2020	Summary
23/04/2020	Act adopted by Council after Parliament's 1st reading		
23/04/2020	Final act signed		
24/04/2020	Final act published in Official Journal		
20/05/2020	End of procedure in Parliament		

Technical information

Procedure reference	2020/0060(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/745 2012/0266(COD)
Legal basis	Rules of Procedure EP 163; Treaty on the Functioning of the EU TFEU 114-p1; Treaty on the Functioning of the EU TFEU 168-p4
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/02754

Documentation gateway

Legislative proposal		COM(2020)0144	03/04/2020	EC	Summary
Text adopted by Parliament, 1st reading/single reading		T9-0053/2020	17/04/2020	EP	Summary
Draft final act		00010/2020/LEX	23/04/2020	CSL	
Commission response to text adopted in plenary		SP(2020)159	13/05/2020	EC	

Final act

Regulation 2020/561
OJ L 130 24.04.2020, p. 0018

Medical devices

PURPOSE: to defer the application of certain provisions of Regulation (EU) 2017/745 on medical devices in order to allow Member States, health establishments and economic operators to give priority to the fight against the coronavirus pandemic.

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 on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2017/745 of the European Parliament and of the Council establishes a new regulatory framework to ensure the proper functioning of the internal market for medical devices. At the same time, it sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such devices. Regulation (EU) 2017/745 significantly reinforces key elements of the existing regulatory approach in Council Directive 90/385/EEC and Council Directive 93/42/EEC, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices, to improve health and safety.

The coronavirus pandemic and the resulting public health crisis represent an unprecedented challenge for Member States and a heavy burden for national authorities, health care institutions and economic operators.

The coronavirus crisis has created exceptional circumstances that require considerable additional resources and increased availability of vitally important medical devices such as medical gloves, surgical masks or intensive care equipment. None of these measures could reasonably have been anticipated at the time of the adoption of the Medical Devices Regulation.

These extraordinary circumstances have a significant impact on different areas covered by the Medical Devices Regulation. It is therefore very likely that Member States, health care institutions, economic operators and other stakeholders would not have been able to ensure its proper implementation and application from the date of application initially foreseen on 26 May 2020.

CONTENT: for exceptional reasons, in the current context of the coronavirus epidemic, the Commission proposes to defer by one year, to 26 May 2021, the date of application of the provisions of Regulation (EU) 2017/745 which should have applied from 26 May 2020.

The proposed amendment aims to achieve the objectives of Regulation (EU) 2017/745, namely the establishment of a rigorous, transparent, predictable and sustainable regulatory framework for medical devices that ensures a high level of protection of public health and patient safety and the proper functioning of the internal market for these devices.

At the same time, it is proposed to defer the date of repeal of Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices by one year. These postponements would ensure that an operational regulatory framework for medical devices

would be in place from 26 May 2020.

In addition, the proposed amendment aims to ensure that, in exceptional cases, the Commission may adopt, as soon as possible, EU-wide derogations following national derogations, in order to effectively address potential shortages of vitally important medical devices in the EU.

In view of the urgent need to respond immediately to the public health crisis related to the COVID-19 pandemic, the proposed amending Regulation should enter into force as a matter of urgency.

Medical devices

The European Parliament adopted a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions.

The European Parliament adopted its position at first reading under the ordinary legislative procedure by means of an urgent procedure.

Parliament supported the proposal to defer for one year (until 26 May 2021) the application of certain provisions of Regulation (EU) 2017/745 on medical devices in order to allow Member States, health establishments and economic operators to give priority to the fight against the coronavirus pandemic by continuing according to current procedures.

Medical devices, such as medical gloves, surgical masks, equipment for intensive care and other medical equipment, play a crucial role in the context of the COVID-19 outbreak and the associated public health crisis to ensure the health and safety of Union citizens and to enable Member States to give necessary medical treatment to patients who are urgently in need of such treatment.

Given the unprecedented magnitude of the current challenges related to COVID-19, it is very likely that Member States, health institutions, economic operators and other relevant parties shall not be in a position to ensure the proper implementation and application of that Regulation from 26 May 2020 as laid down therein.

By way of derogation from Directives 90/385/EEC and 93/42/EEC, it is specified that conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2021. Notified bodies which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2021.