

Basic information	
<p><b>2012/0266(COD)</b></p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Procedure completed
<p>Medical devices</p> <p>Amending Directive 2001/83/EC <a href="#">1999/0134(COD)</a> Amending Regulation (EC) No 178/2002 <a href="#">2000/0286(COD)</a> Amending Regulation (EC) No 1223/2009 <a href="#">2008/0035(COD)</a> See also <a href="#">2012/0267(COD)</a> Amended by <a href="#">2020/0060(COD)</a> Amended by <a href="#">2022/0417(COD)</a> Amended by <a href="#">2023/0005(COD)</a> Amended by <a href="#">2024/0021(COD)</a></p> <p><b>Subject</b></p> <p>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</p>	

Key players				
European Parliament	<b>Committee responsible</b>		<b>Rapporteur</b>	<b>Appointed</b>
	<a href="#">ENVI</a> Environment, Climate and Food Safety		<a href="#">WILLMOTT Dame Glenis (S&amp;D)</a>	16/10/2012
			Shadow rapporteur <a href="#">MCGUINNESS Mairead (PPE)</a> <a href="#">KRAHMER Holger (ALDE)</a> <a href="#">RIVASI Michèle (Verts/ALE)</a> <a href="#">YANNAKOUDAKIS Marina (ECR)</a>	
	<b>Former committee responsible</b>		<b>Former rapporteur</b>	<b>Appointed</b>
	<a href="#">ENVI</a> Environment, Climate and Food Safety		<a href="#">ROTH-BEHRENDT Dagmar (S&amp;D)</a>	16/10/2012
	<b>Former committee for opinion</b>		<b>Former rapporteur for opinion</b>	<b>Appointed</b>
	<a href="#">INTA</a> International Trade		The committee decided not to give an opinion.	
	<a href="#">EMPL</a> Employment and Social Affairs		<a href="#">ESTRELA Edite (S&amp;D)</a>	21/11/2012

	<a href="#">ITRE</a> Industry, Research and Energy	The committee decided not to give an opinion.	
	<a href="#">IMCO</a> Internal Market and Consumer Protection	<a href="#">BERRA Nora (PPE)</a>	10/10/2012
Council of the European Union	<b>Council configuration</b>	<b>Meetings</b>	<b>Date</b>
	General Affairs	3526	2017-03-07
	General Affairs	3484	2016-09-20
	Employment, Social Policy, Health and Consumer Affairs	3475	2016-06-16
	Employment, Social Policy, Health and Consumer Affairs	3323	2014-06-19
	Employment, Social Policy, Health and Consumer Affairs	3206	2012-12-06
	Employment, Social Policy, Health and Consumer Affairs	3351	2014-12-01
	Employment, Social Policy, Health and Consumer Affairs	3280	2013-12-09
European Commission	<b>Commission DG</b>	<b>Commissioner</b>	
	Health and Food Safety	MIMICA Neven	
European Economic and Social Committee			
European Committee of the Regions			

<b>Technical information</b>	
<b>Procedure reference</b>	2012/0266(COD)
<b>Procedure type</b>	COD - Ordinary legislative procedure (ex-codecision procedure)
<b>Procedure subtype</b>	Legislation
<b>Legislative instrument</b>	Regulation
	Amending Directive 2001/83/EC <a href="#">1999/0134(COD)</a> Amending Regulation (EC) No 178/2002 <a href="#">2000/0286(COD)</a> Amending Regulation (EC) No 1223/2009 <a href="#">2008/0035(COD)</a> See also <a href="#">2012/0267(COD)</a> Amended by <a href="#">2020/0060(COD)</a> Amended by <a href="#">2022/0417(COD)</a> Amended by <a href="#">2023/0005(COD)</a> Amended by <a href="#">2024/0021(COD)</a>
<b>Legal basis</b>	Treaty on the Functioning of the EU TFEU 168-p4 Treaty on the Functioning of the EU TFEU 114-p1
<b>Mandatory consultation of other institutions</b>	<a href="#">European Economic and Social Committee</a> <a href="#">European Committee of the Regions</a>
<b>Stage reached in procedure</b>	Procedure completed
<b>Committee dossier</b>	ENVI/8/06745







<b>Documentation gateway</b>				
<b>European Parliament</b>				
<b>Document type</b>	<b>Committee</b>	<b>Reference</b>	<b>Date</b>	<b>Summary</b>

Committee draft report		<a href="#">PE507.972</a>	12/04/2013	
Amendments tabled in committee		<a href="#">PE510.536</a>	26/04/2013	
Amendments tabled in committee		<a href="#">PE510.767</a>	14/05/2013	
Amendments tabled in committee		<a href="#">PE510.766</a>	14/05/2013	
Amendments tabled in committee		<a href="#">PE510.765</a>	14/05/2013	
Amendments tabled in committee		<a href="#">PE510.741</a>	14/05/2013	
Amendments tabled in committee		<a href="#">PE510.666</a>	17/05/2013	
Committee opinion	<a href="#">EMPL</a>	<a href="#">PE506.249</a>	20/06/2013	
Committee opinion	<a href="#">IMCO</a>	<a href="#">PE507.987</a>	08/08/2013	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A7-0324/2013</a>	09/10/2013	<a href="#">Summary</a>
Text adopted by Parliament, partial vote at 1st reading /single reading		<a href="#">T7-0428/2013</a>	22/10/2013	<a href="#">Summary</a>
Text adopted by Parliament, 1st reading/single reading		<a href="#">T7-0266/2014</a>	02/04/2014	<a href="#">Summary</a>
Committee draft report		<a href="#">PE601.098</a>	15/03/2017	
Committee recommendation tabled for plenary, 2nd reading		<a href="#">A8-0068/2017</a>	23/03/2017	<a href="#">Summary</a>
Text adopted by Parliament, 2nd reading		<a href="#">T8-0107/2017</a>	05/04/2017	<a href="#">Summary</a>

#### Council of the EU

Document type	Reference	Date	Summary
Council statement on its position	<a href="#">06592/1/2017</a>	27/02/2017	
Council position	<a href="#">10728/4/2016</a>	08/03/2017	<a href="#">Summary</a>
Draft final act	<a href="#">00014/2017/LEX</a>	05/04/2017	

#### European Commission

Document type	Reference	Date	Summary
Document attached to the procedure	<a href="#">COM(2012)0540</a> 	26/09/2012	<a href="#">Summary</a>
Document attached to the procedure	<a href="#">SWD(2012)0274</a> 	26/09/2012	
Document attached to the procedure	<a href="#">SWD(2012)0273</a> 	26/09/2012	
Legislative proposal	<a href="#">COM(2012)0542</a> 	26/09/2012	<a href="#">Summary</a>
Commission response to text adopted in plenary	<a href="#">SP(2014)471</a>	09/07/2014	
Commission communication on Council's position	<a href="#">COM(2017)0129</a> 	09/03/2017	<a href="#">Summary</a>
Follow-up document	<a href="#">SWD(2024)0076</a>	22/03/2024	
Follow-up document	<a href="#">COM(2024)0560</a> 	29/11/2024	

#### National parliaments

	<a href="#">Parliament</a>			
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Document type	/Chamber	Reference	Date	Summary
Contribution	<a href="#">IT_SENATE</a>	<a href="#">COM(2012)0542</a>	25/10/2012	
<b>Other institutions and bodies</b>				
Institution/body	Document type	Reference	Date	Summary
EDPS	Document attached to the procedure	<a href="#">N7-0042/2014</a> <a href="#">OJ C 358 07.12.2013, p. 0010</a>	08/02/2013	<a href="#">Summary</a>
ESC	Economic and Social Committee: opinion, report	<a href="#">CES2185/2012</a>	14/02/2013	

Additional information		
Source	Document	Date
EP Research Service	<a href="#">Briefing</a>	
EP Research Service	<a href="#">Briefing</a>	
National parliaments	<a href="#">IPEX</a>	
European Commission	<a href="#">EUR-Lex</a>	

Final act
<p><a href="#">Corrigendum to final act 32017R0745R(02)</a> <a href="#">OJ L 334 27.12.2019, p. 0165</a></p> <p><a href="#">Corrigendum to final act 32017R0745R(01)</a> <a href="#">OJ L 117 03.05.2019, p. 0009</a></p> <p><a href="#">Regulation 2017/0745</a> <a href="#">OJ L 117 05.05.2017, p. 0001</a></p>
<a href="#">Summary</a>

Delegated acts	
Reference	Subject
<a href="#">2023/2796(DEA)</a>	Examination of delegated act
<a href="#">2022/2986(DEA)</a>	Examination of delegated act