credible management at EU level with access to internal and external technical, scientific and clinical expertise, allowing improved coordination and resource-sharing between Member States.

Specific objective 2: Enhance transparency regarding medical devices on the EU market, including their traceability.

ABM/ABB activity(ies) concerned

Health for Growth

The Commission's Proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme for the period 2014-2020 (COM[2011]709) lists contribution to the objectives of the EU legislation in the field of medical devices as one of the eligible actions to be financed by the programme.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

On patients and healthcare professionals: High level of human health and safety; cases of deliberate circumvention of the legal requirements (e.g. PIP case) are prevented or quickly identified. High level of transparency and traceability regarding medical devices on the market (e.g. publicly accessible Eudamed; UDI; implant card; summary of safety and performance) allowing better informed decision-making and follow-up. High level of confidence in the EU regulations.

On manufacturers of medical devices: Level playing field due to clearer rules and obligations, benefiting in particular the large majority of manufacturers which already comply with the spirit of the current legislation. Benefits from smoother functioning of the internal market. Support to innovation due to predictable regulatory framework conditions (e.g. early scientific advice). Lower overall administrative burdens due to central registration of devices and reporting of serious incidents.

On notified bodies: Safeguard their role in pre-market medical device assessment. Level playing field due to clearer rules and obligations, benefiting in particular those notified bodies which already comply with the spirit of the current legislation. Reinforcement of their position vis-à-vis manufacturers.

On national authorities: Reinforcement of their enforcement powers. Clear legal framework for coordination between them and resource- and work-sharing.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

Number of patients harmed by unsafe medical devices.

Number of designated notified bodies, their areas of competence and the level of diversification.

Number of registrations (medical devices, economic operators, certificates), incident reports, single applications for clinical investigations and market surveillance measures in the Eudamed databank with its several new electronic systems.

Number of preliminary conformity assessments "called up" under the scrutiny mechanism and number of comments emitted by MDCG.

Number of coordinated actions between national competent authorities regarding post-market safety issues (vigilance and market surveillance).

Number of 'borderline cases' solved.

Number of devices fitted with an UDI system that is aligned with international practice.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The existing regulatory framework is being criticised for not sufficiently ensuring patient safety within the internal market and for being intransparent. The criticism has become even louder after findings of the French health authorities that a French manufacturer (*Poly Implant Prothèse*, PIP) over several years apparently used industrial silicone instead of medical grade silicone for the manufacture of breast implants contrary to the approval provided by the notified body, causing harm to thousands of women around the world.

In an internal market with currently 32 participating countries (EU, EFTA, Turkey) and subject to constant technological and scientific progress, important divergences in the interpretation and application of the rules have emerged, thus undermining the directives' main objectives, i.e. the safety of medical devices and their free circulation within the internal market. Moreover, regulatory gaps or uncertainties exist with regard to certain products (e.g. products manufactured utilising non-viable human tissues or cells; implantable or other invasive products for cosmetic purposes).

The present revision aims to overcome these flaws and gaps and to put in place a robust, transparent and sustainable regulatory framework that is 'fit for purpose'.

1.5.2. Added value of EU involvement

The proposed revision of the existing directives concerning medical devices, which will integrate the modification of the Lisbon Treaty regarding public health, can only be achieved at Union level. The proposals are based on Article 114 and Article 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

EU action is necessary to improve the level of protection of public health for all European patients and users, as well as to prevent Member States from adopting varying product regulations which would result in a further fragmentation of the internal market. Harmonised rules and procedures allow manufacturers, especially SMEs that represent more than 80% of the sector, to reduce costs related to national

regulatory differences, while ensuring a high and equal level of safety for all European patients and users. In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary to achieve those objectives.

1.5.3. Lessons learned from similar experiences in the past

The existing directives concerning medical devices, which date back to the 1990ies, have set harmonised requirements to be met by medical devices placed on the EU market. But they have not provided for mechanisms that ensure a harmonised implementation. As mentioned under 1.5.1., important divergences in the interpretation and application of the rules have emerged, thus undermining the directives' main objectives, i.e. the safety of medical devices and their free circulation within the internal market.

In addition, lessons drawn from an analysis of the shortcomings brought to light by the PIP case have been taken into account for the drafting of these proposals.

1.5.4. Coherence and possible synergy with other relevant instruments

Enhanced coherence is expected with other legislations (e.g. concerning medicinal products, food, biocides, cosmetics) in terms of better delimitation of the respective scopes of application and/or in terms of solution of 'borderline cases'.

Synergies are expected with the legislation regarding medicinal products, in particular as regards the assessment of drug-device combination products and as regards clinical research regarding medicinal products (in the context of the revised Clinical Trials Directive) and regarding medical devices (in the context of this proposal) and/or performance evaluation studies with IVDs (in the context of the proposal for a Regulation on IVDs).

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from 2014 to 2017,

– followed by full-scale operation.

1.7. Management mode(s) envisaged[66]

X Centralised direct management by the Commission

☐ **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive agencies

– ☐ bodies set up by the Communities[67]

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

The Commission intends to ensure the services concerned via centralised direct management through its own services, in particular via the JRC for the technical, scientific and logistic support.

The centralised direct management by the Commission also applies to the further development and management of Eudamed (electronic systems regarding UDI; central registration of medical devices, economic operators and certificates; central reporting of

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66 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

67 As referred to in Article 185 of the Financial Regulation.

vigilance cases; market surveillance measures; clinical investigations) and the IT tool for the notification of information regarding new applications for conformity assessment concerning high risk devices by notified bodies and 'called up' preliminary assessments by them in the context of the scrutiny mechanism.

It should be highlighted that the four **EFTA countries** (via EEA Agreement and MRA with CH) and **Turkey** (via Customs Union Agreement) will participate in the management.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The future Medical Device Coordination Group (MDCG), set up by this Regulation, and its special working groups will provide a regular platform to discuss issues related to the implementation of the new regulatory framework.

Ten years after entry into force, the Commission should report to the European Parliament and to the Council about the achievements of the 'medical device package'. The report should address the impact of the new rules in respect of public health and patient safety, internal market, innovativeness and competitiveness of the medical device industry (with special attention to SMEs). The Commission should consult competent authorities and stakeholders (healthcare professionals, patients, manufacturers, notified bodies) when preparing its report.

2.2. Management and control system

2.2.1. Risk(s) identified

Risks related to Eudamed:

The development of the future Eudamed database would become too complex and would not meet the needs of the national competent authorities, the notified bodies, economic operators and the public at large.

The IT infrastructure would not support the registration of all medical devices placed on the EU market (several hundreds of thousands), or the reporting of serious incidents and field safety corrective actions (several thousands a years), the reporting of market surveillance measures, or the single submission of applications for clinical investigations and the reporting of related serious adverse events.

The non-public parts of the Eudamed database with sensitive personal and commercial information would disclose confidential information, e.g. due to hacking or software failure.

Risks related to the conformity assessment of medical devices:

By the date of application of the new Regulations, an insufficient number of notified bodies would be designated in accordance with the new requirements which would lead to a delay for manufacturers to get their devices approved.

The scrutiny mechanism would be used in a way that would delay, in a disproportionate manner, access to market of innovative medical devices.

The IT tool for the notification of information regarding new applications and/or submission of preliminary assessments by notified bodies, which contains commercially sensitive information, would disclose confidential information, e.g. due to hacking or software failure.

2.2.2. Control method(s) envisaged

Control methods regarding risks related to Eudamed:

The development of Eudamed is given high priority with a high level of sensitivity as regards its functioning.

Close and regular contacts between the Commission services responsible for the management of the regulatory framework and the IT developers.

Close and regular contacts between the Commission services/IT developers and the future users of the IT infrastructure.

Control methods regarding risks related to the conformity assessment of medical devices:

The reinforced and coordinated supervision of notified bodies in the context of the 'immediate action' initiated after the PIP scandal already takes account of the future requirements laid down in the proposal and thus supports a smooth transition.

The Commission shall create guidance to ensure a proportionate and workable operation of the new scrutiny mechanism.

The development of the IT tool is given high priority with a high level of sensitivity as regards its functioning.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, the responsible Commission's services will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS) adopted on 24 June 2011 in order to ensure *inter alia* that its internal anti-fraud related controls are fully aligned with the CASF and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the financing implementing activities of the Medical Devices Regulations will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the financing implementing activities of the Medical Devices Regulations will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;

- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation;

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

Moreover, the Commission will control a strict application of the rules on conflict of interests provided in the proposal.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Operational resources which are necessary for implementation of this initiative will be covered by the allocations proposed under the Health for Growth Programme 2014-2020.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description: Health for Growth Programme]	Diff./non-diff. (68)	from EFTA[69] countries	from candidate countries[70]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
3	17.03.XX.	~~Diff/non-diff.~~	YES/~~NO~~	~~YES~~/NO (to be determined whether Turkey – in the context of the Customs Union and as candidate country – should contribute.)	~~YES~~/NO	~~YES~~/NO

68 Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

69 EFTA: European Free Trade Association.

70 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure (in current prices)

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	Number 3	Citizenship (Health for Growth Programme)

DG SANCO			Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		**TOTAL**
• Operational appropriations[71]										
Number of budget line: 17.03.XX[72]	Commitments	(1)	5,296	5,677	6,667	7,662	7,590	7,742	7,742	**48,376**
	Payments	(2)	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	**48,376**
Appropriations of an administrative nature financed from the envelope for specific programmes[73]										
Number of budget line:		(3)								
TOTAL appropriations for DG SANCO	Commitments	=1+1a +3	5,296	5,677	6,667	7,662	7,590	7,742	7,742	**48,376**
	Payments	=2+2a	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	**48,376**

71 Costs for development of IT and for technical/scientific support.

72 The cost of the action will be entirely covered by the envelope of the Health for Growth programme under the budgetary line related to the relevant objective of the programme.

73 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

		+3								

• TOTAL operational appropriations	Commitments	(4)	5,296	5,677	6,667	7,662	7,590	7,742	7,742	**48,376**
	Payments	(5)	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	**48,376**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADING 3B of the multiannual financial framework	Commitments	=4+ 6	5,296	5,677	6,667	7,662	7,590	7,742	7,742	**48,376**
	Payments	=5+ 6	2,648	5,486	6,172	7,165	7,626	7,666	7,742 + 3,871	**48,376**

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(4)								
	Payments	(5)								
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)								
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6								
	Payments	=5+ 6								

Heading of multiannual financial framework:	5	" Administrative expenditure "

EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		TOTAL
DG SANCO									
• Human resources		2,413	2,413	2,413	2,413	2,413	2,413	2,413	**16,891**
• Other administrative expenditure		0,469	0,478	0,488	0,497	0,508	0,519	0,519	**3,478**
TOTAL DG SANCO	Appropriations	2,882	2,891	2,901	2,910	2,921	2,932	2,932	**20,369**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	2,882	2,891	2,901	2,910	2,921	2,932	2,932	**20,369**

EUR million (to 3 decimal places)

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years		TOTAL
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	8,178	8,568	9,568	10,572	10,511	10,674	10,674	**68,745**
	Payments	5,530	8,377	9,073	10,075	10,547	10,598	10,674 + 3,871	**68,745**

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– **X** The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ⇩			Year 2014		Year 2015		Year 2016		Year 2017		Year 2018		2019 et sq years				**TOTAL**	
	OUTPUTS																	
	Type of output[74]	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1			Establish mechanisms to ensure harmonised implementation of the rules by all Member States with a sustainable, efficient and credible management at EU level with access to internal and external technical, scientific and clinical expertise, allowing improved coordination and resource-sharing between Member States															
- Output	Meetings of MDCG		80 meeting days	1,873	80 meeting days	1,910	80 meeting days	1,948	80 meeting days	1,987	80 meeting da	2,027	80 meeting days	2,068	80 meeting days	2,068		13,881
- Output	Technical and scientific opinions and advice			0,406		0,690		1,580		2,473		2,523		2,573		2,573		12,818

74 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

- Output	Audits / 'joint assessments' of 80 notified bodies			0,416		0,424		0,433		0,442		0,450		0,459		0,459		3,083
Sub-total for specific objective N°1				2,695		3,024		3,961		4,902		5,000		5,100		5100		29,782
SPECIFIC OBJECTIVE No 2			Enhance transparency regarding medical devices on the EU market, including their traceability																	
- Output	Eudamed (with 6 electronic systems: UDI, registration, certificates, clinical inv., vigilance, market surv.), as of 2018 with statistical analysis / business intelligence) for signal detection		1	2,081	1	2,122	1	2,165	1	2,208	1	2,027	1	2,068	1	2,068		14,739
- Output	Translations, info campaigns, publications etc.		tbd	0,520	tbd	0,531	tbd	0,541	tbd	0,552	tbd	0,563	tbd	0,574	tbd	0,574		3,855
Sub-total for specific objective N°2				2,601		2,653		2,706		2,760		2,590		2,642		2,642		18,594
Total costs				5,296		5,677		6,667		7,662		7,590		7,742		7,742		**48,376**

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of administrative appropriations

– **X** The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	2019 et sq years	**TOTAL**
HEADING 5 of the multiannual financial framework							
Human resources	2,413	2,413	2,413	2,413	2,413	2,413	2,413	**16,891**
Other administrative expenditure	0,469	0,478	0,488	0,497	0,508	0,519	0,519	**3,478**
Subtotal HEADING 5 of the multiannual financial framework	2,882	2,891	2,901	2,910	2,921	2,932	2,932	**20,369**

Outside HEADING 5[75] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	2,882	2,891	2,901	2,910	2,921	2,932	2,932	**20,369**

[75] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– **X** The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year >2019
• **Establishment plan posts (officials and temporary agents)**							
17 01 01 01 (Headquarters and Commission's Representation Offices)	19	19	19	19	19	19	19
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
10 01 05 01 (Direct research)							
• **External personnel (in Full Time Equivalent unit: FTE)**[76]							
XX 01 02 01 (CA, INT, SNE from the "global envelope")							
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)							
XX 01 04 *yy* [77] - at Headquarters[78]							
XX 01 04 *yy* [77] - in delegations							
XX 01 05 02 (CA, INT, SNE - Indirect research)							
10 01 05 02 (CA, INT, SNE - Direct research)							
Other budget lines (specify)							
TOTAL	**19**	**19**	**19**	**19**	**19**	**19**	**19**

XX is the policy area or budget title concerned.

The human resources required will be met by staff from DG SANCO who are already assigned to the management of the action and who will be redeployed within DG SANCO, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints (estimated needs: 16 AD/FTE and 3 AST/FTE).

Description of tasks to be carried out:

Officials and temporary agents	Control of appropriate implementation of this Regulation; development of delegated/implementing acts and guidance; development of new electronic systems for Eudamed (in cooperation with IT staff); organisation and direction of 'joint assessments' of notified bodies and control of designation and monitoring process by Member States; coordination of market surveillance activities with EU wide impact; follow-up of national safeguard and preventive health protection measures;

[76] CA= Contract Agent; INT= agency staff (*"Intérimaire"*); JED= *"Jeune Expert en Délégation"* (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

[77] Under the ceiling for external personnel from operational appropriations (former "BA" lines).

[78] Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

	international regulatory cooperation; management of Medical Device Committee (committee within the meaning of Reg. 182/2011).
External personnel	

3.2.4. Compatibility with the current multiannual financial framework

– **X** Proposal/initiative is compatible with the new multiannual financial framework 2014-2020.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[79].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties

– The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	… enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations cofinanced								

[79] See points 19 and 24 of the Interinstitutional Agreement.

3.3. Estimated impact on revenue

– ☐ Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

– 1. on own resources

– 2. on miscellaneous revenue

EUR million (to 3 decimal places)

Budget revenue line:	Appropriations available for the ongoing budget year	Impact of the proposal/initiative[80]						
		2014	2015	2016	2017	Subsequent years		
Article		0	0	0	0	0	0	0

For miscellaneous assigned revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

[80] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.

Council of the
European Union

Brussels, 11 June 2015
(OR. en)

9769/15

Interinstitutional File:
2012/0266 (COD)

PHARM 26
SAN 176
MI 391
COMPET 304
CODEC 858

NOTE

From:	Presidency
To:	Council
No. prev. doc.:	9238/15 PHARM 22 SAN 155 MI 347 COMPET 259 CODEC 775 + COR1
No. Cion doc.:	14493/12 PHARM 71 SAN 215 MI 597 COMPET 600 CODEC 2305 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on **medical devices** and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Delegations will find in the Annex to this document a consolidated text for the Articles of the proposed Regulation mentioned above prepared by the Latvian Presidency with a view to the meeting of the Council (EPSCO) on 19 June 2015.

At its meeting on 10 June 2015, the Permanent Representatives Committee agreed to forward the text in the Annex to this Note to the Council with a view to reaching a Partial General Approach (excluding recitals).

New text compared to the Commission proposal is written in ***bold italics***. Deletions are marked by ~~strikethrough~~.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

Chapter I

Scope and definitions

Article 1

Scope

1. This Regulation ~~establishes~~ ***lays down*** rules ~~to be complied with by medical devices and accessories to medical devices that are placed~~ ***concerning the placing on the market, making available*** on the market or put***ting*** into service ***of medical devices and accessories to medical devices for human use*** in the Union ~~for human use~~. ***This regulation also applies to clinical investigations on medical devices conducted in the Union.***

1a. This regulation shall also apply to the groups of products without an intended medical purpose that are listed in Annex XV as from the date of entry into force of common specifications or the date of application of this Regulation, whichever is the latest, adopted pursuant to Article 7, taking into account the state of the art, and in particular existing standards for analogous devices with a medical purpose, based on a similar technology. The common specifications for a group of products listed in that annex shall address, at least, application of risk management and of the general safety and performance requirements set out in Annex I and clinical evaluation.

The necessary Common Specifications shall be adopted as soon as possible following entry into force of this Regulation and at the latest so that they enter into force on the date of application of this Regulation.