Upon completing the manufacture of each batch of devices that incorporate a medicinal substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of Article 1(4), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 114(2) of Directive 2001/83/EC.

7. Administrative provisions

The manufacturer or his authorised representative shall, for a period ending at least five years, and in the case of implantable devices at least 15 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the documentation referred to in Section 2,
- the certificate referred to in Section 5.2,
- the EU type-examination certificate referred to in Annex IX.

Section 9 of Annex VIII shall apply.

8. Application to devices classified as class IIa

8.1. By way of derogation from Section 1, by virtue of the EU declaration of conformity the manufacturer ensures and declares that the devices in class IIa are manufactured in conformity with the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them.

8.2. The verification conducted by the notified body in accordance with Section 4 is intended to confirm the conformity of the devices in class IIa with the technical documentation referred to in Annex II and with the requirements of this Regulation which apply to them.

8.3. If the verification in accordance with Section 8.2. confirms that the devices in class IIa conform to the technical documentation referred to in Annex II and meet the requirements of this Regulation which apply to them, the notified body shall issue a certificate pursuant to this section of this Annex.

8.4. By way of derogation from Section 7, the manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the declaration of conformity,
- the technical documentation referred to in Annex II,

– the certificate referred to in Section 8.3.

Section 9 of Annex VIII shall apply.

ANNEX XI

CONFORMITY ASSESSMENT PROCEDURE FOR CUSTOM-MADE DEVICES

1. For custom-made devices the manufacturer or his authorised representative shall draw up the statement containing the following information:

   - the name and address of the manufacturer, and of any additional manufacturing sites,
   - if applicable, the name and address of the authorised representative,
   - data allowing identification of the device in question,
   - a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code,
   - the name of the doctor of medicine, dental practitioner or any other person authorised by national law by virtue of this person's professional qualifications who made out the prescription and, where applicable, the name of the health institution concerned,
   - the specific characteristics of the product as indicated by the prescription,
   - a statement that the device in question conforms to the general safety and performance requirements set out in Annex I and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds,
   - where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Commission Regulation (EU) No 722/2012.

2. The manufacturer shall undertake to keep available for the competent national authorities the documentation, indicating manufacturing site(s) and allowing an understanding of the design, manufacture and performances of the product, including the expected performances, so as to allow assessment of conformity with the requirements of this Regulation.

   The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces products which are manufactured in accordance with the documentation mentioned in the first paragraph;

3. The information contained in the declaration concerned by this Annex shall be kept for a period of time of at least five years after the device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

   Section 9 of Annex VIII shall apply.

4. The manufacturer shall undertake to review and document experience gained in the post-production phase, including a PMCF referred to in Part B of Annex XIII, and to implement appropriate means to apply any necessary corrective action. This undertaking shall include an obligation for the manufacturer to notify, in accordance with Article 61(4) the competent authorities of any serious incidents and/or field safety corrective actions immediately on learning of them.

ANNEX XII

MINIMUM CONTENT OF CERTIFICATES ISSUED BY A NOTIFIED BODY

1. Name, address and identification number of the notified body;

2. name and address of the manufacturer and, if applicable, of the authorised representative;

3. unique number identifying the certificate;

4. date of issue;

5. date of expiry;

6. data needed for the identification of the device(s) or categories of devices covered by the certificate, including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);

7. if applicable, the manufacturing facilities covered by the certificate;

8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;

9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);

10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;

11. if applicable, information about the surveillance by the notified body;

12. conclusions of the notified body's assessment, examination or inspection;

13. conditions for or limitations to the validity of the certificate;

14. legally binding signature of the notified body according to the applicable national law.

ANNEX XIII

CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

PART A: CLINICAL EVALUATION

1. To conduct a clinical evaluation, a manufacturer shall:

   - identify the general safety and performance requirements that require support from relevant clinical data;
   - identify available clinical data relevant to the device and its intended use generated through scientific literature search, clinical experience and/or clinical investigations;
   - appraise the clinical data sets by evaluating their suitability for establishing the safety and performance of the device;
   - generate any new or additional clinical data needed to address outstanding issues;
   - analyse all relevant clinical data to reach conclusions about the safety and performance of the device.

2. Confirmation of conformity with the requirements concerning the characteristics and performances referred to in Section 1 of Annex I, under the normal conditions of use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on clinical data.

3. The clinical evaluation shall be thorough and objective, considering both favourable and unfavourable data. Its depth and extent shall be proportionate and appropriate to the nature, classification, intended use, manufacturer's claims and risks of the device in question.

4. Clinical data relating to another device may be relevant where equivalence is demonstrated of the device subject to clinical evaluation to the device to which the data relates. Equivalence can only be demonstrated when the device that is subject to clinical evaluation and the device to which the existing clinical data relates have the same intended purpose and when the technical and biological characteristics of the devices and the medical procedures applied are similar to such an extent that there would be not a clinically significant difference in the safety and performance of the devices.

5. In the case of implantable devices and devices falling within class III, clinical investigations shall be performed unless it is duly justified to rely on existing clinical data alone. Demonstration of equivalence in accordance with Section 4 shall generally not be considered as sufficient justification within the meaning of the first sentence of this paragraph.

6. The results of the clinical evaluation and the clinical data on which it is based shall be documented in the clinical evaluation report which shall support the assessment of the conformity of the device.

The clinical data together with non-clinical data generated from non-clinical testing methods and other relevant documentation shall allow the manufacturer to demonstrate conformity with the general safety and performance requirements and shall be part of the technical documentation of the device in question.

PART B: POST-MARKET CLINICAL FOLLOW-UP

1. Post-market clinical follow-up, hereinafter: PMCF, is a continuous process to update the clinical evaluation referred to in Article 49 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan. To this end, the manufacturer shall proactively collect and evaluate clinical data from the use in or on humans of a device which is authorised to bear the CE marking, within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, the continued acceptability of identified risks and to detect emerging risks on the basis of factual evidence.

2. The PMCF shall be performed pursuant to a documented method laid down in a PMCF plan.

2.1. The PMCF plan shall specify the methods and procedures to proactively collect and evaluate clinical data with the aim of

(a) confirming the safety and performance of the device throughout its expected lifetime,

(b) identifying previously unknown side-effects and monitoring the identified side-effects and contra-indications,

(c) identifying and analysing emergent risks on the basis of factual evidence,

(d) assuring the continued acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, and

(e) identifying possible systematic misuse or off-label use of the device with a view to verify the correctness of its intended purpose.

2.2. The PMCF plan shall lay down, in particular

(a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;

(b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;

(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);

(d) a reference to the relevant parts of the clinical evaluation report referred to in Section 6 of Part A of this Annex and to the risk management referred to in Section 2 of Annex I;

(e) the specific objectives to be addressed by the PMCF;

(f) an evaluation of the clinical data related to equivalent or similar devices,

(g) reference to relevant standards and guidance on PMCF.

3. The manufacturer shall analyse the findings of the PMCF and document the results in a PMCF evaluation report that shall be part of the technical documentation.

4. The conclusions of the PMCF evaluation report shall be taken into account for the clinical evaluation referred to in Article 49 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMCF the need for corrective measures has been identified, the manufacturer shall implement them.

ANNEX XIV

CLINICAL INVESTIGATIONS

I. General requirements

1. Ethical considerations

Every step in the clinical investigation, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly in Helsinki, Finland, in 1964, and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.

2. Methods

2.1. Clinical investigations shall be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims for the device as well as the safety, performance and benefit/risk related aspects referred to in Article 50(1); these investigations shall include an adequate number of observations to guarantee the scientific validity of the conclusions.

2.2. The procedures used to perform the investigations shall be appropriate to the device under examination.

2.3. Clinical investigations shall be performed in circumstances similar to the normal conditions of use of the device.

2.4. All the appropriate features, including those involving the safety and performances of the device, and its effect on patients shall be examined.

2.5. The investigations shall be performed under the responsibility of a medical practitioner or another authorised qualified person in an appropriate environment.

2.6. The medical practitioner or other authorised person shall have access to the technical and clinical data regarding the device.

2.7. The clinical investigation report, signed by the medical practitioner or other authorised person responsible, shall contain a critical evaluation of all the data collected during the clinical investigation, including negative findings.

II. Documentation regarding the application for clinical investigation

For investigational devices covered by Article 50 the sponsor shall draw up and submit the application in accordance with Article 51 accompanied by the documentation as laid down below:

1. Application form

The application form shall be duly filled in, containing information regarding:

1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person established in the Union.

1.2. If different from the Section 1.1., name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of his authorised representative.

1.3. Title of the clinical investigation.

1.4. Single identification number in accordance with Article 51(1).

1.5. Status of the clinical investigation (e.g. first submission, resubmission, significant amendment).

1.6. If resubmission with regard to same device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission.

1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No [.../...] [on clinical trials on medicinal products for human use], reference to the official registration number of the clinical trial.

1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical investigation shall be conducted as part of a multicentre/multinational study at the time of application.

1.9. Brief description of the investigational device (e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII).

1.10. Information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative, or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives.

1.11. Summary of the clinical investigation plan (objective(s) of the clinical investigation, number and gender of subjects, criteria for subject selection, subjects under 18 years of age, design of the investigation such as controlled and/or randomised studies, planned dates of commencement and of completion of the clinical investigation).

1.12. If applicable, information regarding a comparator (e.g. identification of the comparator device or medicinal product).

2. Investigator's Brochure

The investigator's brochure (IB) shall contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application. It shall be clearly identified and contain in particular the following information:

2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.

2.2. Manufacturer's instructions for installation, and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available.

2.3. Pre-clinical testing and experimental data, in particular regarding in design calculations, *in vitro* tests, *ex vivo* tests, animal tests, mechanical or electrical tests, reliability tests, software verification and validation, performance tests, evaluation of biocompatibility and biological safety.

2.4. Existing clinical data, in particular

- of the relevant scientific literature available relating to the safety, performance, design characteristics and intended purpose of the device and/or of equivalent or similar devices;

- of other relevant clinical data available relating to the safety, performance, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance and safety related issues and any corrective actions taken;

2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contra-indications and warnings.

2.6. In the case of devices that incorporates a medicinal substance, including a human blood or plasma derivative, or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the medicinal substance or on the tissues or cells, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues or cells.

2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.

2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.

3. Clinical Investigation Plan

The clinical investigation plan (CIP) shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical investigation. It shall contain in particular the information as laid down below. If part of this information is submitted in a separate document, it shall be referenced in the CIP.

3.1. General

3.1.1. Identification of the clinical investigation and the CIP.

3.1.2. Identification of the sponsor.

3.1.3. Information on the principal investigator, coordinating investigator, including their qualifications, and on the investigation site(s).

3.1.4. Overall synopsis of the clinical investigation.

3.2. Identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use.

3.3. Justification for the design of the clinical investigation.

3.4. Risks and benefits of the device and of the clinical investigation.

3.5. Objectives and hypotheses of the clinical investigation.

3.6. Design of the clinical investigation

3.6.1. General information such as type of investigation with rationale for choice, endpoints, variables.

3.6.2. Information on the device to be used for the clinical investigation, on any comparator and on any other device or medication.

3.6.3. Information on subjects, including size of investigation population and, if applicable, information on vulnerable populations.

3.6.4. Description of the procedures related to the clinical investigation.

3.6.5. Monitoring plan.

3.7. Statistical considerations.

3.8. Data management.

3.9. Information about any amendments to the CIP.

3.10. Policy regarding deviations from the CIP.

3.11. Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices.

3.12. Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical investigations of medical devices as well as with the applicable regulatory requirements.

3.13. Informed consent process.

3.14. Safety reporting, including definitions of adverse events and serious adverse events, procedures and timelines for reporting.

3.15. Criteria and procedures for suspension or early termination of the clinical investigation.

3.16. Policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.

3.17. Bibliography.

4. Other information

4.1. A signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject.

This statement may be supported by an attestation issued by a notified body.

4.2. Where applicable according to national law, copy of the opinion(s) of the ethics committee(s) concerned as soon as available.

4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to the national law.

4.4. Documents and procedures to be used to obtain informed consent.

4.5. Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:

- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;
- a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical investigations;
- a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.

III. Other sponsor's obligations

1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the investigational device, this obligation may be fulfilled by that person on behalf of the sponsor.

2. The reportable events shall be provided by the investigator(s) in timely conditions.

3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical investigation with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market. In the case of implantable devices the period shall be at least 15 years.

Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.

ANNEX XV

LIST OF PRODUCTS COVERED BY THE LAST SUBPARAGRPAH OF THE DEFINITION OF 'MEDICAL DEVICE' REFERRED TO IN NUMBER (1) OF ARTICLE 2(1)

1. Contact lenses;
2. Implants for modification or fixation of body parts;
3. Facial or other dermal or mucous membrane fillers;
4. Equipment for liposuction;
5. Invasive laser equipment intended to be used on the human body;
6. Intense pulsed light equipment.

ANNEX XVI

CORRELATION TABLE

Council Directive 90/385/EEC	**Council Directive 93/42/EEC**	**This Regulation**
Article 1(1)	Article 1(1)	Article 1(1)
Article 1(2)	Article 1(2)	Article 2(1)
Article 1(3)	Article 1(3) 1st subparagraph	Article 1(5)1st subparagraph
-	Article 1(3) 2nd subparagraph	Article 1(5)2nd subparagraph
Article 1(4) and (4a)	Article 1(4) and (4a)	Article 1(4)1st subparagraph
Article 1(5)	Article 1(7)	Article 1(6)
Article 1(6)	Article 1(5)	Article 1(2)
-	Article 1(6)	-
	Article 1(8)	Article 1(7)
Article 2	Article 2	Article 4(1)
Article 3 1st subparagraph	Article 3 1st subparagraph	Article 4(2)
Article 3 2nd subparagraph	Article 3 2nd subparagraph	-
Article 4(1)	Article 4(1)	Article 22
Article 4(2)	Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 4(3)	Article 19(3)
Article 4(4)	Article 4(4)	Article 8(7)
Article 4(5) point (a)	Article 4(5) 1st subparagraph	Article 18(6)
Article 4(5) point (b)	Article 4(5) 2nd subparagraph	-
Article 5(1)	Article 5(1)	Article 6(1)
Article 5(2)	Article 5(2)	Article 6(2)
Article 6(1)	Article 5(3), Article 6	-
Article 6(2)	Article 7(1)	Article 88

Article 7	Article 8	Articles 69 to 72
-	Article 9	Article 41
Article 8(1)	Article 10(1)	Number (43) and (44) of Article 2(1), Article 61(1), Article 63(1)
Article 8(2)	Article 10(2)	Article 61(3) and Article 63(1)2nd subparagraph
Article 8(3)	Article 10(3)	Article 63(2) and (4)
Article 8(4)	Article 10(4)	Article 66
Article 9(1)	Article 11(1)	Article 42(2)
-	Article 11(2)	Article 42(4)
-	Article 11(3)	Article 42(3)
-	Article 11(4)	-
-	Article 11(5)	Article 42(5)
Article 9(2)	Article 11 (6)	Article 42(7)
Article 9(3)	Article 11(8)	Article 9(3)
Article 9(4)	Article 11(12)	Article 42(8)
Article 9(5)	Article 11(7)	-
Article 9(6)	Article 11(9)	Article 43(1)
Article 9(7)	Article 11(10)	Article 43(3)
Article 9(8)	Article 11(11)	Article 45(2)
Article 9(9)	Article 11(13)	Article 47(1)
Article 9(10)	Article 11(14)	-
-	Article 12	Article 20
-	Article 12a	Article 15
Article 9a(1) 1st indent	Article 13(1) point (c)	-
Article 9a(1) 2nd indent	Article 13(1) point (d)	Article 3(1)
-	Article 13(1) point (a)	Article 41(3)

-	Article 13(1) point (b)	Article 41(4) point (a)
Article 10	Article 15	Articles 50 to 60
Article 10a	Article 14	Article 25
Article 10b	Article 14a	Article 27
Article 10c	Article 14b	Article 74
Article 11(1)	Article 16(1)	Articles 33 and 34
Article 11(2)	Article 16(2)	Article 29
Article 11(3)	Article 16(3)	Article 36(2)
Article 11(4)	Article 16(4)	-
Article 11(5)	Article 16(5)	Article 45(4)
Article 11(6)	Article 16(6)	Article 45(3)
Article 11(7)	Article 16(7)	Articles 31(2) and 35(1)
Article 12	Article 17	Article 18
Article 13	Article 18	Article 73
Article 14	Article 19	Article 75
Article 15	Article 20	Article 84
Article 15a	Article 20a	Article 77
Article 16	Article 22	-
Article 17	Article 23	-
-	Article 21	-

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

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

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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.

This financial statement also includes the costs related to the Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices which is based on the same organisational and IT infrastructure established by this Proposal.

1.2. Policy area(s) concerned in the ABM/ABB structure[64]

Health for Growth

1.3. Nature of the proposal/initiative

X The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[65]

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

In the field of medical devices, the proposals aim

1) to ensure a high level of **human health and safety**,

2) to ensure the functioning of the **internal market**, and

3) to promote **innovation** in medical technology for the benefit of patients and healthcare professionals.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective 1: Establish mechanisms to ensure harmonised implementation of the rules on medical devices by all Member States with a sustainable, efficient and

64 ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

65 As referred to in Article 49(6)(a) or (b) of the Financial Regulation.