Article 82

Conflict of interests

1. Members of the MDCG, ***its sub-groups,*** and staff of the EU reference laboratories shall not have financial or other interests in the medical device industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner. They shall declare any direct and indirect interests they may have in the medical device industry and update this declaration whenever a relevant change occurs. Upon request, the declaration of interests shall be accessible to the public. This Article shall not apply to the representatives of stakeholder organisations participating in the sub-groups of the MDCG.

2. Experts and other third parties invited by the MDCG on a case-by-case basis shall ~~be requested to~~ declare ~~their~~ ***any*** interests ***they may have*** in the issue in question.

Article 83

Device registers

The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers for specific types of devices ~~to gather post-market experience related to the use of such devices~~ ***setting common principles to collect comparable information***. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices ***and/or to the traceability of implantable devices***.

Chapter IX

Confidentiality, data protection, funding, penalties

Article 84

Confidentiality

1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on ~~medical~~ confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:
   (a) personal data in compliance with ***Article 85*** ~~Directive 95/46/EC and Regulation (EC) No 45/2001~~;
   (b) commercial***ly confidential information*** ~~interests~~ ***and trade secrets*** of a natural or legal person, including intellectual property rights; ***unless disclosure is the public interests***;
   (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.

2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall ~~remain confidential unless~~ ***shall not be disclosed without prior agreement with*** the originating authority ~~has agreed to its disclosure~~.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 85

Data protection

1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.

2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission pursuant to this Regulation.

Article 86

Levy of fees

1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles. ~~They~~

2. ***Member States*** shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.

Article ~~40~~ 86a

~~Fees~~ Funding of notified body designation and monitoring activities

~~1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.~~

1a. The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).

~~2. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 setting out the structure and the level of the fees referred to in paragraph 1, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 31(2) and notified bodies that are small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.~~

Article 87

Penalties

The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [*3 months prior to the date of application of the Regulation*] and shall notify it without delay of any subsequent amendment affecting them.

Chapter X
Final provisions

Article 88

Committee procedure

1. The Commission shall be assisted by a Committee on Medical Devices. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.

Article 89

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Articles 2(2) and (3), 4~~(5)~~, 8(2), 17(4), 24(7***a***), ~~25(7), 29(2), 40(2), 41(4),~~ 42(11), 45(5)~~, 51(7), 53(3), 74(4)~~ and ~~81(6),~~ ***81a(10)*** is conferred on the Commission subject to the conditions laid down in this Article. ***When adopting those delegated acts, the Commission shall follow its usual practice and carry out consultations with experts, including Member States' experts.***

2. The delegation of power referred to in Articles 2(2) and (3), ~~4(5),~~ 8(2), 17(4), 24(7***a***), ~~25(7),~~ ~~29(2), 40(2), 41(4),~~ 42(11), 45(5)~~, 51(7), 53(3), 74(4),~~ and ~~81(6),~~ ***81a(10)*** shall be conferred on the Commission for ~~an indeterminate period of time~~ ***a period of five years*** from the date of entry into force of this Regulation. ***The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

3. The delegation of power referred to in Articles 2(2) and (3), ~~4(5),~~ 8(2), 17(4), 24(7***a***), ~~25(7),~~ ~~29(2), 40(2), 41(4),~~ 42(11), 45(5)~~, 51(7), 53(3), 74(4)~~ and ~~81(6),~~ ***81a(10)*** may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of ~~two~~ ***three*** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by ~~two~~ ***three*** months at the initiative of the European Parliament or the Council.

~~*Article 90*~~

~~*Urgency procedure for delegated acts*~~

~~1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.~~

~~2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 89. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.~~

Article 90a

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 91

Amendments to Directive 2001/83/EC

In Annex I of Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

'(12) Where a product is governed by this Directive in accordance with the second subparagraph of Article 1(4) or the second subparagraph of Article 1(5) of Regulation (EU) [.../...] on medical devices, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) [.../...], the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question~~, unless the authority is advised by its experts for medical devices that involvement of a notified body is not required~~.'

Article 92

Amendments to Regulation (EC) No 178/2002

In the third subparagraph of Article 2 of Regulation (EC) No 178/2002, the following point (i) is added:

'(i) medical devices within the meaning of Regulation (EU) [.../...]'

Article 93

Amendments to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

'4. In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition 'cosmetic product'.'

Article 94

Transitional provisions

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation.

   Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

3. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [*date of application*] until [*18 months after date of appl*ication], comply with Article 25(2) and (3) and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.

6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

7. Devices falling within the scope of this Regulation in accordance with point (e) of Article 1(2) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation may continue to be placed on the market and put into service in the Member States concerned.

8. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to the application of this Regulation may continue to be conducted. As of the application of this Regulation, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

9. Until the Commission in line with Article 24(2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.

Article 95

Evaluation

No later than seven years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation.

Article 96

Repeal

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from [***the later of the two dates referred to in Article 97(2) and 97(3)(d)***] ~~[*date of application of this Regulation*]~~, with the exception of Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC which are repealed with effect from ***18 months after the later of the two dates referred to in Article 97(2) and 97(3)(d)*** ~~[*18 months after date of application*]~~.

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI.

Article 97

Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union.*

2. It shall apply from [*three years after entry into force*].

3. By way of derogation from paragraph 2 the following shall apply:

(a) Article 25(2) and (3) and Article 45(4) shall apply from [*18 months after date of application referred to in paragraph 2*];

(b) Articles 28 to 40 and Article 78 shall apply from [*six months after entry into force*]. However, prior to [*date of application as referred to in paragraph 2*], the obligations on notified bodies emanating from the provisions in Articles 28 to 40 shall apply only to those bodies which submit an application for notification in accordance with Article 31 of this Regulation.

(c) For implantable devices and Class III devices Article 24(4) shall apply one year after the date of application of this regulation. For Class IIa and Class IIb devices Article 24(4) shall apply three years after the date of application of this regulation. For Class I devices Article 24(4) shall apply five years after the date of application of this regulation.

(ca) For reusable devices that shall bear the UDI Carrier on the device itself, Article 24(4) shall apply two years after the date applicable for its class of devices as stipulated in point (c).

(d) Articles 24 to 27, Chapter VI, Article 60c(2), Article 65a and Article 66a shall apply from six months after the publication of the notice referred to in Article 27a(3), but in any event no earlier than the point in time referred to in paragraph 2.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, ~~26.9.2012~~

For the European Parliament *For the Council*

The President *The President*