Amendment 263
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 8 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Manufacturers shall ensure that ***the device is accompanied by*** the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.	7. Manufacturers shall ensure that the information to be supplied ***for the device*** in accordance with Section 17 of Annex I ***is provided*** in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.
For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.	For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the ***official Union*** language(s) of the Member State where the device reaches its intended user.

Or. en

Justification

It should be possible to provide the information electronically. It needs to be specified, that the information shall be provided in official union languages and not any other language. Both changes reduce the potential burden for SMEs.

Amendment 264
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***translated into*** the official Union ***language or languages required by the Member State(s) in which the device is made available.***	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be ***issued in one of*** the official Union languages.

Or. en

Justification

Generally, translation of declarations of conformity into all official Union languages where the device is made available is a disproportionate administrative and thus cost-intensive effort, especially for SMEs which is not justified. Like under the current directive, availability in one Union language should be sufficient.

Amendment 265
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Annex II – point 3.2 – point b

Text proposed by the Commission	*Amendment*
(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.	(b) identification of all sites, including suppliers and sub-contractors, where ***critical*** manufacturing activities are performed.

Or. en

Justification

Should be harmonized with GHTF-Document "Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices"

Amendment 266
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Annex III – point 7

Text proposed by the Commission	*Amendment*
7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;	***deleted***

Or. en

Justification

The reference to the harmonized standards and the applied parts of standards is made in the technical documentation and can be examined by the public authorities with all the items of evidence. The continuous need for changes by updating the standards in the declaration of conformity would be immense - without generating any extra value concerning patient safety or safety of the devices in general. It is a huge burden for the manufacturers and should therefore be deleted to avoid overburden bureaucracy.

Amendment 267
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Annex VI – point 3. 5 a. 2. (new)

Text proposed by the Commission	*Amendment*
	3. 5a. 2. Product Specialists for Special Notified Bodies
	The personnel responsible for carrying out product related reviews (e.g. design dossier review, technical documentation review or type examination) for devices referred to in Article 41 a shall have the following proven Product Specialist qualification:
	- Meet the requirement for Product Assessors;
	- Have an advanced academic degree in a field relevant to medical devices, or alternatively have six years of relevant experience in in vitro diagnostic medical devices or related sectors;
	- Have an ability to identify key risks of products within the specialist's product categories without prior reference to manufacturer's specifications or risk analyses;
	- Have an ability to assess the essential requirements in the absence of harmonised or established national standards;
	- The professional experience should be gained in the first product category their qualification is based on, relevant to the product category of designation of the

notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use , with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;

- Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;

- For product specialists with qualifications in specific technology, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.

For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Article 41a(1). For those devices, product specialists shall be available in house for the designated technology fields covered by the scope of notification.

Or. en

Amendment 268
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 1 – paragraph 6

Text proposed by the Commission	*Amendment*
6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.	6. This Regulation ***provides that certain devices may only be supplied on a medical prescription but*** it shall not affect national laws which require that certain ***other*** devices may also only be supplied on a medical prescription. ***Direct to consumer advertising of devices classed as prescription only by this Regulation shall be illegal.*** ***The following devices may only be supplied on a medical prescription:*** ***1) Class D devices;*** ***2) Class C devices in the following categories:*** ***(a) devices for genetic testing;*** ***(b) companion diagnostics.*** ***By derogation, justified by the attainment of a high level of public health protection, Members States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission.*** ***The Commission shall be empowered to***

adopt delegated acts in accordance with Article 85 to decide that other class C tests may only be supplied on a medical prescription after consultation with stakeholders.

Or. en

Amendment 269
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 44 a (new)

Text proposed by the Commission	*Amendment*
	Article 44 a (new)
	Additional assessment procedure in extraordinary cases
	1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a.
	2. Within 20 days of receipt of the

information referred to in paragraph 1, the MDCG may decide to request the special notified body to submit the following documents prior to issuing a certificate:

- the clinical evidence report and the clinical performance study report as referred to in Annex XII,

- data obtained from the post market follow-up referred to in Annex XII, and

- any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by competent authorities in those countries,

The members of the MDCG shall decide on making such a request on the basis of the following criteria:

(a) the novelty of the device with possible major clinical or health impact

(b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;

(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices;

In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these

criteria.

In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file.

In the absence of a request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.

3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.

4. In its opinion the MDCG shall take into account the clinical assesment of the ACMD. The MDCG may recommend modifications of the documents referred to in paragraph 2.

5. The MDCG shall inform the Commission, the Special notified body and the manufacturer of its opinion.

6. Within 15 days after receipt of the opinion referred to in paragraph 5, the Special notified body shall indicate whether or not it agrees with the opinion

of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, the Special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information to the Commission

Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion.

7. Immediately after its adoption, the MDCG shall send its final opinion to the Commission, the Special notified body and the manufacturer.

8. In case of a favourable MDCG opinion, the special notified body may proceed with the certification.

However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaptation of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented.

Following the adoption of a favourable opinion, the Commission shall always explore the possibility of adopting, common technical standards for the device of group of devices concerned and adopt them where possible.

In case of an unfavourable MDCG opinion, the special notified body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different to that which has

been previously submitted the MDCG shall reassess the application.

At the request of the manufacturer, the Commission shall organise a hearing allowing discussion on the scientific grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.

9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time.

Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.

10. The Commission shall make a summary of the opinion referred to in paragraphs 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.

11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the Special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.

12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination

procedure referred to in Article 84(3).

13. The company concerned shall not be charged for the additional costs due to this assessment.

Or. en

Amendment 270
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Recital 59 a (new)

Text proposed by the Commission	*Amendment*
	59a. Whereas, in view of the need to protect the integrity of the human person during the sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine.

Or. en

Justification

Re-establishing of the wording from the current directive.

Amendment 271
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Article 4 a (new)

Text proposed by the Commission	*Amendment*
	Article 4a
	Genetic information, counselling and informed consent
	1. A device may only be used for the purpose of a genetic test if the indication is given by persons admitted to the medical profession under the applicable national legislation after a personal consultation.
	2. A device may be used for purposes of a genetic test only in a way that the rights, safety and well-being of the subjects are protected and that the clinical data generated in the course of the genetic testing are going to be reliable and robust.
	3. Information. Before using a device for the purpose of a genetic test the person mentioned in paragraph 1 shall provide the person concerned with appropriate information on the nature, the significance and the implications of the genetic test.
	4. Genetic counselling. Appropriate genetic counselling is mandatory before using a device for the purpose of predictive and prenatal testing and after a

genetic condition has been diagnosed. It shall include medical, ethical, social, psychological and legal aspects and has to be addressed by physicians or another person qualified under national law in genetic counselling.

The form and extent of this genetic counselling shall be defined according to the implications of the results of the test and their significance for the person or the members of his or her family.

5. Consent. A device may only be used for the purpose of a genetic test after the person concerned has given free and informed consent to it. The consent has to be given explicitly and in writing. It can be revoked at any time in writing or orally.

6. Testing of minors and incapacitated subjects. In case of minors the informed consent of the parents or legal representative or minors themselves shall be obtained in accordance with national laws; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor. In case of incapacitated subjects not able to give informed legal consent, the informed consent of the legal representative shall be obtained; consent must represent the presumed will of the incapacitated subject and may be revoked at any time, without detriment to the person.

7. A device may only be used for the determination of sex in connection with prenatal diagnosis, if the determination fulfils a medical purpose and if there is a risk of serious gender specific hereditary diseases. By way of derogation from Article 2(1) and (2) this also applies to products which are not intended to fulfil a specific medical purpose.

8. The provisions of this Article on the use

of devices for the purpose of genetic tests do not prevent the Member States from maintaining or introducing for reasons of health protection or public order more stringent national legislation in this field.

Or. en

Amendment 272
Peter Liese
on behalf of the PPE Group

Report **A7-0327/2013**
Peter Liese
In vitro diagnostic medical devices
COM(2012)0541 – C7-0317/2012 – 2012/0267(COD)

Proposal for a regulation
Recital 67 b (new)

Text proposed by the Commission	*Amendment*
	(67b) Whereas, although internationally certified reference materials and materials used for external quality assessment schemes are not covered by this Directive, calibrators and control materials needed by the user to establish or verify performances of devices are in vitro diagnostic medical devices.

Or. en

Justification

Re-establishing of the wording from the current directive.