RULES OF PROCEDURE
OF THE MEDICAL DEVICE COORDINATION GROUP

The Medical Device Coordination Group (hereinafter the "MDCG"),

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC1, and in particular Article 103(8) thereof, which established the MDCG,

Having regard to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in-vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU[2], and in particular Article 98 thereof,

Having regard to the standard rules of procedure of expert groups[3],

Has adopted the following Rules of Procedure:

Point 1
Operation of the MDCG

1. The MDCG acts in accordance with provisions of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the horizontal rules on the creation and operation of Commission expert groups[4], the Terms of Reference, and the present Rules of Procedure.
2. Members of the MDCG are experts representing the competent authorities of the Member States. Member States shall notify the names and the affiliation of the appointed members and their alternates in writing to the MDCG secretariat.
3. The MDCG shall be chaired by a representative of DG Internal Market, Industry, Entrepreneurship and SMEs.
4. The MDCG may decide to set up a coordination group to assist the Commission in activities related to management of the MDCG.

Point 2
Working groups

1. The MDCG may create permanent or *ad-hoc* sub-groups (hereinafter, working groups) to discuss specific topics, on the basis of terms of reference defined by the MDCG for each working group. *Ad hoc* working groups shall be dissolved as soon as their mandate is fulfilled.
2. In order to ensure timely and efficient exercise of its competences laid down in Regulation (EU) 2017/745 and Regulation (EU) 2017/746, the MDCG may delegate certain tasks to a working group, in accordance with the terms of reference of the working group. The delegation can be withdrawn anytime.
3. Member States shall appoint members to the working groups and notify in writing their names and the affiliation to the MDCG secretariat. Member States may appoint alternate

[1] OJ L 117, 5.5.2017, p. 1.
[2] OJ L 117, 5.5.2017, p. 176.
[3] Commission Decision C(2016) 3301 (Annex 3).
[4] Commission Decision C(2016) 3301.

members to the working groups, in accordance with the terms of reference of the working group.

4. The working groups shall be chaired by a representative of the Commission. Where appropriate, the working groups may be co-chaired by a member of the working group.
5. When necessary, Chairs or co-Chairs of the working groups that are not members of the MDCG may be invited to attend the MDCG meetings.
6. The working groups shall report to the MDCG.

Point 3

Third countries, experts and other third parties

1. Iceland, Liechtenstein, Norway, Switzerland and Turkey shall have an observer status in the MDCG and its working groups.
2. In agreement with the Commission services, an observer status may be granted to candidate countries and to other non-EU countries where it is in the interest of the EU that such country is involved in the works of the MDCG, in particular based on an international agreement, an administrative arrangement or EU legislation.
3. The observers referred to in paragraphs 1 and 2 shall notify in writing the names and the affiliation of their representatives to the MDCG secretariat. They may also appoint an alternate representative, in which case they shall notify that person to the MDCG secretariat.
4. The observers referred to in paragraphs 1 and 2 shall have the right to participate in the meetings of the MDCG and its working groups, take part in the discussions and provide expertise, however, they shall not have voting rights and they shall not participate in the formulation of positions of the MDCG or, as appropriate, a working group.
5. The Chair of the MDCG or, as appropriate, of a working group, acting on request of the MDCG or, as appropriate, of a working group, may invite, on a case-by-case basis, experts and other third parties with a specific competence in a subject on the agenda to participate in the meetings or provide written contributions. The Chair of a working group shall inform the MDCG about any such invited experts or other third parties, indicating the meeting and the reason for the invitation to that meeting.

Point 4

Stakeholders

1. Organisations representing the interests of the medical device industry, other economic operators, healthcare professionals, conformity assessment bodies, hospitals, laboratories, patients and consumers at Union level (hereinafter, the stakeholders) may be given an observer status in the MDCG and/or a working group either by a direct invitation by the Chair, or following a call for applications, as appropriate.
2. Following an invitation from the Chair of the MDCG, stakeholders with an observer status may be invited to attend an open information session of the MDCG or a part thereof.
3. Stakeholders attending sessions of the MDCG or its working groups may be permitted by the Chair to take part in the discussions and provide expertise, however they shall not have voting rights and they shall not participate in the formulation of positions of the MDCG or, as appropriate, a working group.
4. The Chair of the MDCG, or, as appropriate, the Chair of a working group, acting on his own initiative or on a proposal of a member, may invite, on a case-by-case basis, a

stakeholder without the observer status to attend an open session of the MDCG or the working group or a part thereof or to provide a written contribution.

Point 5
Meetings

1. Plenary meetings of the MDCG shall be convened by the Chair. When the situation requires, extraordinary meetings shall be convened either on the Chair's own initiative or at the request of appointed MDCG members in consultation with the Chair.
2. The meetings of the working groups are convened by the Chair of the respective working group.
3. The members of the MDCG and working groups may be accompanied by national experts, subject to agreement of the Chair. Within a reasonable period of time before the date of a meeting, the names and functions of the experts shall be communicated to the Chair. National experts shall not represent the members and shall not have voting rights.
4. The MDCG and its working groups shall meet either in physical meetings or for audio or videoconferences. Physical meetings of the MDCG and its working groups shall, in principle, be held on the Commission's premises.
5. The Chair of the MDCG may decide to convene a joint meeting of the MDCG and any of its working groups. The Chairs of any of the working groups may decide to convene a joint meeting of the working groups.

Point 6
Agenda

1. The secretariat shall draw up the agenda under the responsibility of the Chair of the MDCG, or, as appropriate, the Chair of a working group, and submit it to the members of the MDCG or the working group.
2. The agenda shall indicate which agenda points are for information and discussion, on which agenda points a position should be adopted, and it shall include a list of documents for respective agenda points, if available.
3. Any member of the MDCG or a working group may propose a new item on the agenda.
4. The agenda shall be adopted by the MDCG or the working group at the start of the meeting.

Point 7
Documentation for the meeting

1. The secretariat shall send the invitation to the meeting, the draft agenda and the documents to be adopted during the meeting to the members of the MDCG or a working group no later than 14 calendar days before the date of the meeting.
2. In urgent or exceptional cases, the time limit laid down in paragraph 1 may be reduced to at least 3 calendar days before the date of the meeting.
3. Paragraphs 1 and 2 do not apply to documents to be presented at the meeting for information or discussion purposes only.

Point 8
Positions and deliberations

1. As far as possible, and unless otherwise specified in the Terms of Reference or these

Rules of Procedure, the MDCG or its working groups shall act by consensus.

2. In the event of a vote, the outcome of the vote shall be decided by simple majority of all appointed members. The members that have voted against or abstained shall have the right to have their position and the grounds on which it is based recorded in the overall position.
3. The appointment of one or two members or alternates to the MDCG as provided for in the Terms of Reference does not affect the voting rights, which shall be one per Member State.
4. The alternates shall represent and vote for the members of the MDCG in their absence. A Member State may represent a maximum of one other Member State if a member from that Member State or his alternate does not participate in a meeting of the MDCG. The Member State that is being represented shall inform the Chair of this before the meeting, or, at the latest, before the vote.
5. The Chair of the MDCG or the Chair of a working group representing the Commission shall not take part in the voting.
6. In agreement with the Chair, the MDCG or any of its working groups may, by simple majority of all appointed members, decide that a meeting or its part shall be public.
7. For recommendations and opinions pursuant to Articles 39(9) and 42(7) of Regulation (EU) 2017/745 and Articles 35(9) and 38(7) of Regulation (EU) 2017/746, a member of the MDCG may be appointed as a rapporteur, to prepare a draft position of the MDCG. A co-rapporteur may also be appointed.

Point 9
Written procedure

1. If necessary, the MDCG position on a specific question may be delivered *via* a written procedure. To this end, the secretariat sends the MDCG members the document(s) on which the MDCG is being consulted. Provisions of points 7 and 8 apply as appropriate.
2. The secretariat shall inform MDCG members of the outcome of the written procedure.
3. However, if a simple majority of all appointed MDCG members asks for the question to be examined at a meeting of the MDCG, and provided that the postponement of that examination is not considered by the Chair to adversely affect any significant public interests or the smooth implementation of Regulation (EU) 2017/745 or Regulation (EU) 2017/746, the written procedure shall be terminated without result and the Chair shall convene a meeting of the MDCG as soon as possible.
4. Provisions of this point apply to the working groups of the MDCG as appropriate.

Point 10
Minutes of the meetings

1. Minutes on the discussion on each point on the agenda and on the positions delivered by the MDCG or a working group shall be meaningful and complete.
2. Minutes shall be drafted by the secretariat under the responsibility of the Chair of the MDCG, or, as appropriate, the Chair of a working group.

Point 11
Attendance list

At each meeting, the secretariat shall draw up an attendance list, under the responsibility of the Chair of the MDCG, or, as appropriate, the Chair of a working group. The list shall

specify, as appropriate, the Member State's authorities, organisations, or other entities to which participants belong.

Point 12
Support to the MDCG

The Commission services shall provide technical, scientific and logistic support for the MDCG and any of its working groups.

Point 13
Conflicts of interest

1. In accordance with Article 107(1) of Regulation (EU) 2017/745, members of the MDCG and working groups and their alternates shall not have financial or other interests in the medical device industry, whether direct or indirect, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner.
2. For this purpose, the members and the alternates shall make a declaration of interests at the beginning of their term, in accordance with Annex 1, and update that declaration whenever a relevant change occurs. The declarations of interests shall be published on the Register of expert groups.
3. The declaration of interests referred to in paragraph 2 shall be also made by observers and their alternates representing non-EU countries in accordance with point 3 paragraphs 1-3.
4. An affirmative answer in the declaration made in accordance with the above paragraphs does not automatically mean a conflict of interest. Any such affirmative answer shall be brought by the Chair of the MDCG or, as appropriate, of the working group to the attention of the MDCG, in order for the MDCG to determine whether a conflict of interest exists. For the purpose of the assessment, a number of factors shall be taken into account, including the nature, type and magnitude of the individuals' interest, as well as the degree to which interest may be reasonably expected to influence the individual's position. The MDCG may decide to contact the individual in question in order to obtain any additional information that may be needed for the assessment of any conflict of interest. A position of the MDCG as to whether a conflict of interest exists shall be recorded and implemented, in accordance with MDCG instructions.
5. Any new circumstances which may result in a situation of conflicts of interest by the members or their alternates, observers or the alternate observers, with regard to any particular item on the agenda or with regard to position held in the MDCG or in the working group in general, shall brought to the attention of the MDCG, assessed, recorded and implemented in accordance with paragraph 4. Pending the position of the MDCG as to whether a conflict of interest exists, the individual in question shall refrain from participating in a meeting or in formulation of any particular position of the MDCG or its working group, as appropriate.
6. In accordance with Article 107(2) of Regulation (EU) 2017/745, prior to a meeting or when providing a written contribution, experts and other third parties referred to in point 3 paragraph 5 shall declare any interests they may have in the issue in question, in accordance with Annex 2.

Point 14
Correspondence

1. Correspondence relating to the MDCG or any of its working groups shall be addressed to

the secretariat, for the attention of the Chair of the MDCG or, as appropriate, the Chair of a working group.

2. Correspondence to the members, their alternates, observers, and any other third parties shall be sent to the e-mail address which they provide for that purpose.

Point 15

Transparency

1. The MDCG and its working groups shall be registered on the Register of expert groups.
2. As concerns the composition of the MDCG and its working groups, the following data shall be published on the Register of expert groups:
   a) the names of the members and their alternates, and their affiliation, in accordance with Article 103(2) of Regulation (EU) 2017/745;
   b) the declarations of interests of the members and their alternates, in accordance with Article 107(2) of Regulation (EU) 2017/745;
   c) the names of observers and any appointed alternate observers referred to in point 3, and their affiliation;
   d) the declarations of interests of observers and any appointed alternate observers referred to in point 3;
   e) the names of observers referred to in point 4.
3. In accordance with Article 26 of Commission Decision C(2016) 3301, the secretariat shall make available all relevant documents, including the agendas, the minutes and the participants' submissions, either on the Register of expert groups or *via* a link from the Register to a dedicated website, where this information can be found. Access to dedicated websites shall not be submitted to user registration or any other restriction. In particular, the secretariat shall publish the agenda and other relevant background documents in due time ahead of the meeting, followed by timely publication of minutes. Exceptions to publication shall only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) No 1049/2001[5].

Point 16

Access to documents

Applications for access to documents held by the MDCG or its working groups shall be handled in accordance with Regulation (EC) No 1049/2001.

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[5] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

ANNEX 1

DECLARATION OF INTERESTS OF A MEMBER / AN ALTERNATE FROM EU MEMBER STATE [OR] AN OBSERVER/ALTERNATE OBSERVER FROM NON-EU COUNTRY IN THE MDCG / WORKING GROUP

Legal basis:

Articles **103(8)** and **107(1)** of Regulation (EU) 2017/745

Definitions:

"**Conflict of interest**" means any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest in relation to the subject of the work of the Medical Device Coordination Group or a working group.

"**Immediate family member**" means the individual's spouse, children and parents. "Spouse" includes a partner with whom the individual has a registered non marital regime. "Children" means the child(ren) the individual and the spouse have in common, the own child(ren) of the individual and the own child(ren) of the spouse.

"**Legal entity**" means any commercial business, conformity assessment body, industry association, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources. It also includes independent own commercial businesses, law offices, consultancies or similar.

"**Body**" means a governmental, international or non-profit organisation.

"**Meeting**" includes a series or cycle of meetings.

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Please answer each of the questions below. If the answer to any of the questions is "yes", please briefly describe relevant interests and circumstances, as appropriate.

If you do not describe relevant interests, your DOI form will be considered incomplete and, therefore, you may not participate in the work of the MDCG/working group.

Please note that having a declared interest does not necessarily mean having a conflict of interest. Answering "Yes" to a question on this DOI form does not automatically disqualify you or limit your status in the MDCG or its working group. The MDCG will review your answers in accordance with the Rules of Procedure of the MDCG and determine whether a conflict of interest relevant to the subject at hand exists.

First name and surname:
Name of the national authority of affiliation:
Country:
Member/alternate of the MDCG / working group: *[please specify]*
Observer/alternate observer in the MDCG / working group: *[please specify]*

1 EMPLOYMENT, CONSULTANCY AND LEGAL REPRESENTATION

	Within the past 5 years, were you employed or have you had any other professional relationship with a natural or legal entity, or held any non-remunerated post in a legal entity or other body with an interest in the medical device industry?	**yes**	**no**
1a	**Employment**	☐	☐
1b	**Consultancy, including services as an advisor**	☐	☐
1c	**Non-remunerated post**	☐	☐
1d	**Legal representation**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of entity or body**	**Description**

2 MEMBERSHIP OF MANAGING BODY, SCIENTIFIC ADVISORY BODY OR EQUIVALENT STRUCTURE

	Within the past 5 years, have you participated in the internal decision-making of a legal entity or other body with an interest in the medical device industry or have you participated in the works of a scientific advisory body with voting rights on the outputs of that entity?	**yes**	**no**
2a	**Participation in a decision-making process**	☐	☐
2b	**Participation in the work of a scientific advisory body**	☐	☐

Activity	Time period (from… until month/year)	Name of legal entity or body	Description

3 RESEARCH SUPPORT

	Within the past 5 years, have you, or the research entity to which you belong, received any support from a legal entity or other body with an interest in the medical device industry?	**yes**	**no**
3a	**Research support, including grants, rents, sponsorships, fellowships, non-monetary support**	☐	☐

Activity	Time period (from… until month/year)	Name of legal entity or body	Description

4 FINANCIAL INTERESTS

	Do you have current investments in a legal entity with an interest in the medical device industry, including holding of stocks and shares, and which amounts to more than 10,000 EUR per legal entity or entitling you to a voting right of 5% or more in such legal entity?	**yes**	**no**
4a	**Shares**	☐	☐
4b	**Other stock**	☐	☐

Investment	Name of legal entity	Description

5 INTELLECTUAL PROPERTY

	Do you have any intellectual property rights that might be affected by the outcome of the work carried out by the MDCG or any of its working groups?	**yes**	**no**
5a	**Patent, trademarks, or copyrights**	☐	☐
5b	**Others**	☐	☐

Intellectual property	**Description**

6 PUBLIC STATEMENTS AND POSITIONS

	Within the past 5 years, have you provided any expert opinion or testimony in the field of activity of the MDCG, for a legal entity or other body with an interest in the medical device industry, as part of a regulatory, legislative or judicial process? Have you held an office or other position, paid or unpaid, where you defended an opinion/represented interests the medical device industry?	**yes**	**no**
6a	**For a legal entity or other body as part of a regulatory, legislative or judicial process**	☐	☐
6b	**Represented interests or defended an opinion**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

7 INTERESTS OF IMMEDIATE FAMILY MEMBERS

		yes	**no**
7a	**To your knowledge, are there any interests of your immediate family members which could be seen as undermining your independence when participating in the works of the MDCG / a working group?**	☐	☐

Interests	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

7b	If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in the DOI and to provide them with the privacy statement attached to the guidance for filling in this DOI, and this at the latest when you file the DOI form with the Commission.

8 OTHER RELEVANT INFORMATION

		yes	**no**
8a	**Are there any other elements that could be seen as undermining your independence when participating in the works of the MDCG / a working group?**	☐	☐

Description:

I declare on my honour that the information disclosed in this form is true and complete to the best of my knowledge.

Should there be any change to the above information, including as regards upcoming activities, I will promptly notify the secretariat of the MDCG and complete a new DOI form describing the changes in question.

I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) No 45/2001.

Date: _____ Signature: _____

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In accordance with Article 107(1) of Regulation (EU) 2017/745, your DOI form shall be made publicly available on the Register of Commission Expert Groups and Other Similar Entities, as long as you are appointed to the MDCG or any of its working groups. Technical measures will be taken to indicate to search engines that your DOI form should not appear in search results.

ANNEX 2

DECLARATION OF INTERESTS OF AN EXPERT / A THIRD PARTY PARTICIPAING IN THE WORKS OF MDCG / WORKING GROUP IN ACCORDANCE WITH ARTICLE 103(6) MDR

Legal basis:

Articles **103(8)** and **107(2)** of Regulation (EU) 2017/745

Definitions:

"**Conflict of interest**" means any situation where an individual has an interest that may compromise or be reasonably perceived to compromise the individual's capacity to act independently and in the public interest in relation to the subject of the work of the Medical Device Coordination Group or a working group.

"**Immediate family member**" means the individual's spouse, children and parents. "Spouse" includes a partner with whom the individual has a registered non marital regime. "Children" means the child(ren) the individual and the spouse have in common, the own child(ren) of the individual and the own child(ren) of the spouse.

"**Legal entity**" means any commercial business, conformity assessment body, industry association, consultancy, research institution or other enterprise whose funding is significantly derived from commercial sources. It also includes independent own commercial businesses, law offices, consultancies or similar.

"**Body**" means a governmental, international or non-profit organisation.

"**Meeting**" includes a series or cycle of meetings.

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Please answer each of the questions below. If the answer to any of the questions is "yes", please briefly describe relevant interests and circumstances, as appropriate.

If you do not describe relevant interests, your DOI form will be considered incomplete and, therefore, you may not participate in the work of the MDCG/working group.

Please note that having a declared interest does not necessarily mean having a conflict of interest. Answering "Yes" to a question on this DOI form does not automatically disqualify you or limit your participation in the works of the MDCG or its working group. The MDCG will review your answers in accordance with the Rules of Procedure of the MDCG and determine whether a conflict of interest relevant to the subject at hand exists.

First name and surname:
Name of the organisation of affiliation:
Country:
Expert / third party: *[please specify]*

1 EMPLOYMENT, CONSULTANCY AND LEGAL REPRESENTATION

	Within the past 5 years, were you employed or have you had any other professional relationship with a natural or legal entity, or held any non-remunerated post in a legal entity or other body with an interest in the medical device industry?	**yes**	**no**
1a	**Employment**	☐	☐
1b	**Consultancy, including services as an advisor**	☐	☐
1c	**Non-remunerated post**	☐	☐
1d	**Legal representation**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of entity or body**	**Description**

2 MEMBERSHIP OF MANAGING BODY, SCIENTIFIC ADVISORY BODY OR EQUIVALENT STRUCTURE

	Within the past 5 years, have you participated in the internal decision-making of a legal entity or other body with an interest in the medical device industry or have you participated in the works of a scientific advisory body with voting rights on the outputs of that entity?	**yes**	**no**
2a	**Participation in a decision-making process**	☐	☐
2b	**Participation in the work of a scientific advisory body**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

3 RESEARCH SUPPORT

	Within the past 5 years, have you, or the research entity to which you belong, received any support from a legal entity or other body with an interest in the medical device industry?	**yes**	**no**
3a	**Research support, including grants, rents, sponsorships, fellowships, non-monetary support**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

4 FINANCIAL INTERESTS

	Do you have current investments in a legal entity with an interest in the medical device industry, including holding of stocks and shares, and which amounts to more than 10,000 EUR per legal entity or entitling you to a voting right of 5% or more in such legal entity?	**yes**	**no**
4a	**Shares**	☐	☐
4b	**Other stock**	☐	☐

Investment	**Name of legal entity**	**Description**

5 INTELLECTUAL PROPERTY

	Do you have any intellectual property rights that might be affected by the outcome of the work carried out by the MDCG or any of its working groups?	**yes**	**no**
5a	**Patent, trademarks, or copyrights**	☐	☐
5b	**Others**	☐	☐

Intellectual property	**Description**

6 PUBLIC STATEMENTS AND POSITIONS

		yes	no
	Within the past 5 years, have you provided any expert opinion or testimony in the field of activity of the MDCG, for a legal entity or other body with an interest in the medical device industry, as part of a regulatory, legislative or judicial process? Have you held an office or other position, paid or unpaid, where you defended an opinion/represented interests the medical device industry?		
6a	**For a legal entity or other body as part of a regulatory, legislative or judicial process**	☐	☐
6b	**Represented interests or defended an opinion**	☐	☐

Activity	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

7 INTERESTS OF IMMEDIATE FAMILY MEMBERS

		yes	no
7a	**To your knowledge, are there any interests of your immediate family members which could be seen as undermining your independence when participating in the works of the MDCG / a working group?**	☐	☐

Interests	**Time period (from… until month/year)**	**Name of legal entity or body**	**Description**

7b	If interests of your immediate family members are declared, it is your responsibility to inform them about the collection and publication of information on their interests included in the DOI and to provide them with the privacy statement attached to the guidance for filling in this DOI, and this at the latest when you file the DOI form with the Commission.

8 OTHER RELEVANT INFORMATION

		yes	no
8a	**Are there any other elements that could be seen as undermining your independence when participating in the works of the MDCG / a working group?**	☐	☐

Description:

I declare on my honour that the information disclosed in this form is true and complete to the best of my knowledge.

I am informed that my personal data are stored, processed and published by the Commission in accordance with Regulation (EC) No 45/2001.

Date: _____ Signature: _____