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## Guidance for submission and conduct of a clinical investigation with a medical device or a performance evaluation with an in vitro diagnostic in accordance with § 40 of the Austrian Medical Devices Act as amended

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**NOTE:** The English translations of Austrian legal documents are not authorized and therefore not legally binding. The original, legally binding, German text passages are included in the text for your reference.

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## **Guidance for submission and conduct of a clinical investigation with a medical device or a performance evaluation with an in vitro diagnostic in accordance with § 40 of the Austrian Medical Devices Act as amended**

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### **1. PREREQUISITES FOR THE CONDUCT OF A CLINICAL INVESTIGATION WITH A MEDICAL DEVICE (MD) OR A PERFORMANCE EVALUATION WITH AN IN VITRO DIAGNOSTIC (IVD)**

#### **1.1. When is the project a clinical investigation (CI)/performance evaluation (PE) according to the medical device legislation?**

- a. When the definition of a CI/PE according to medical device legislation is fulfilled (see Annex I for definitions)
- b. When the investigational product is a medical device / an In-vitro-Diagnostic (IVD) according to the medical device definition (see Annex I for definitions) and is being systematically evaluated in study participants

**OR**

when the investigational product is no medical device/IVD, but fulfills the definition of a medical device/IVD through the objectives of the research project and is being systematically evaluated in study participants

The definition of a CI/PE is not fulfilled, if

- a. the medical device(s) used in the undertaking is/are not under investigation, carries/carry a CE mark and is/are used according to its/their intended use (i.e. used as tools)
- b. Data are evaluated only retrospectively according to the study protocol and based on existing datasets obtained in clinical routine; Further, the undertaking does not require prospective patient visits, all diagnostic measures have already been conducted and historic measures taken have not been performed with a view to this data analysis.

*Note:* The objectives of the project are essential to determine the legal positioning of the undertaking

#### **1.2. When is a submission of a clinical investigation to the Agency required?**

A CI is under jurisdiction of the Austrian National Agency if the study sites are located in Austria.

Not all CIs need to be submitted to the agency. A submission is required if one of the following points apply:

- a. The investigated medical device does not carry a CE-mark
- b. The investigated medical device has a CE mark, but is used outside its intended use (see definition in Annex I) in the clinical investigation
- c. The investigated device has a CE-mark and is investigated within its intended use, but the investigation requires additional diagnostic or therapeutic measures, e.g. to obtain new pathophysiological knowledge.
- d. The investigated device is an active implantable medical device (AIMD)
- e. A prototype is being investigated to generate clinical data
- f. The legal framework does not provide for exemptions for early/experimental settings. Therefore reporting requirements equally apply to investigations systematically evaluating medical devices with the purpose of obtaining proof-of-concept data, i.e. pilot studies, proof of concept studies or basic research
- g. the goal of the investigation is to generate data that justify a deviation from/expansion of the intended use of the medical device

#### **1.3. When is submission of a performance evaluation (PE) to the agency required?**

A PE is under jurisdiction of the Austrian National Agency if sample collection takes place in Austria.

- a. The in IVD is not CE marked and /or is used outside its intended use
- b. the PE of a CE marked IVD necessitates additional sampling (type, volume, duration) i.e. is not restricted to residual samples or additional diagnostic or therapeutic measures are planned
- c. the PE is conducted with the purpose of developing, optimizing or validating an IVD

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- d. the goal of the PE is to generate data that justify a deviation from/expansion of the intended use of the IVD

Only data obtained within legally compliant CIs/PEs can rightfully be used as the basis for the reliable and safe application of a medical device/IVD (i.e. for conformity assessment by a notified body).

### Note on "intended use":

Medical devices are utilized outside their intended use in case of deviation with regards to the indication, patient population, disease severities or phase, or combination with other medical devices; further, if applied as part of other or changed medical procedures, if handled by a different user group (.e.g. lay people), in different environmental settings or other changes compared to the intended use.

The intended use is reflected in the conditions for use, in information/advertising leaflets, in product specific internet information and the technical documentation for the device. Special reference needs to be made to the certified mechanism of action and claim by the manufacturer.

## 2. NOTIFICATION PROCEDURES

**MPG § 40 (1)** *Der Sponsor hat bei klinischen Prüfungen von Medizinprodukten das im Anhang 6 der Richtlinie 90/385/EWG, im Anhang VIII der Richtlinie 93/42/EWG, bei der Leistungsbewertungsprüfung von In-vitro-Diagnostika das im Anhang VIII der Richtlinie 98/79/EG angeführte Verfahren anzuwenden.*

**MPG § 40 (1)** In the case of clinical investigations with medical devices, the sponsor shall follow the procedure detailed in Annex 6 of Directive 90/385/EEC and in Annex VIII of Directive 93/42/EEC; in the case of performance evaluations with in vitro diagnostics, the sponsor shall follow the procedure detailed in Annex VIII of Directive 98/79/EC.

The responsibility of classifying a study lies with the sponsor/applicant, the responsibility of classifying a device lies with the manufacturer.

The following websites provide information on the classification of medical devices:

- Classification according to Annex IX Directive 93/42/EWG:  
<http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:01993L0042-20071011&from=EN>
- Classification of IVDs in Annex II of Directive 98/79/EG  
[eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0079-20120111&qid=1413308118275&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0079-20120111&qid=1413308118275&from=EN)

The Austrian Medical Devices Act as amended (Medizinproduktegesetz, MPG) specifies the following procedures for the assessment of CIs/PEs by the Federal Office for Safety in Health Care (BASG) - see also Annex II of this guidance:

### 2.1. Investigations according to § 40 (2) MPG

§ 40 (2) MPG applies to studies with high risk medical devices, in particular

- Active implantable medical devices
- Class III medical devices
- Class IIa or IIb implantable medical devices
- Class IIa or IIb long-term invasive medical devices

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**§ 40 (2) MPG** *Mit der klinischen Prüfung von aktiven implantierbaren Medizinprodukten gemäß Richtlinie 90/385/EWG sowie von Medizinprodukten der Klasse III oder implantierbaren oder zur langzeitigen Anwendung bestimmten invasiven Medizinprodukten der Klassen IIa oder IIb gemäß Richtlinie 93/42/EWG kann nach befürwortender Stellungnahme durch die zuständige Ethikkommission und Erstattung einer ordnungsgemäßen Meldung an das Bundesamt für Sicherheit im Gesundheitswesen begonnen werden, sofern das Bundesamt für Sicherheit im Gesundheitswesen nicht innerhalb einer Frist von 60 Tagen nach ordnungsgemäßer Meldung der klinischen Prüfung die klinische Prüfung zum Schutz der Prüfungsteilnehmer, der öffentlichen Gesundheit oder wegen sonstigen Nichtvorliegens der Voraussetzungen des § 41 Abs. 4 untersagt oder vor Ablauf dieser Frist die Durchführung der klinischen Prüfung genehmigt hat.*

**§ 40 (2) MPG** Clinical investigations with active implantable medical devices in accordance with Directive 90/385/EEC as well as medical devices falling within Class III or implantable and long-term invasive devices falling within Classes IIa or IIb in accordance with Directive 93/42/EEC may commence after the competent ethics committee has issued a favourable opinion and an adequate and complete notification has been submitted to the Federal Office for Safety in Health Care, provided that the Federal Office for Safety in Health Care has not, within a period of 60 days after submission of an adequate and complete notification, prohibited the clinical investigation on considerations of the protection of the subjects enrolled in the investigation, public health, or no fulfilment of other prerequisites detailed in § 41 (4) or has approved the clinical investigation within that 60-day period.

After the competent ethics committee(s) has/have issued a favourable opinion and a valid submission has been received by the BASG, the CI may commence either:

- a. after the 60 day timeline, calculated from the date of written confirmation of valid submission, has expired (tacit approval = Nicht-Untersagungsverfahren) or
- b. upon written notification of BASG approval of the CI within the 60-day assessment period (administrative decision = Bescheid)

### 2.2. Investigations according to § 40(3) MPG

§ 40 (3) MPG applies to investigations with products of average risk and PEs with IVDs, in particular those that are not referred to in § 40 (2) or (5) MPG:

- all classes of IVDs
- Class I medical devices
- Class IIa/IIb medical devices: use under 30 days and non-invasive
- Class IIa/IIb medical devices: use under 30 days and invasive
- Class IIa/IIb medical devices: use more than 30 days and non-invasive

**§ 40 (3) MPG** *Mit der klinischen Prüfung von Medizinprodukten gemäß Richtlinie 93/42/EWG, die nicht in Abs. 2 und 5 genannt sind, und der Leistungsbewertungsprüfungen von In-vitro-Diagnostika gemäß Richtlinie 98/79/EG, die nicht in Abs. 5 genannt sind, kann nach befürwortender Stellungnahme durch die zuständige Ethikkommission und Erstattung einer ordnungsgemäßen Meldung an das Bundesamt für Sicherheit im Gesundheitswesen begonnen werden.*

**§ 40 (3) MPG** Clinical investigations with medical devices in accordance with Directive 93/42/EEC not referred to in paragraphs 2 and 5 and performance evaluations with in vitro diagnostics in accordance with Directive 98/79/EC not referred to in paragraph 5 may commence after the competent ethics committee has issued a favourable opinion and an adequate and complete submission has been submitted to the Federal Office for Safety in Health Care.

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The clinical investigation or performance evaluation may commence after the competent ethics committee(s) has/have issued a favourable opinion and the BASG has confirmed a valid submission

### 2.3. Studies according to § 65a (2) MPG

§ 65a (2) MPG applies exclusively to PEs with IVDs (all classes)

- List A IVDs
- List B IVDs
- IVDs for home-use
- General Class IVDs
- In-house IVDs

**§ 65a. (1) MPG** Die Regelungen der §§ 39, 40 Abs. 1, 3, 4, 5 und 7, 40a und 40b, 41 bis 44, 45 Abs. 2, 46 bis 64 gelten auch für Leistungsbewertungsprüfungen, sofern Abs. 2 nicht anders bestimmt.

(2) Sofern im Rahmen einer Leistungsbewertungsprüfung eines In-vitro-Diagnostikums nicht eine nach Art oder Menge spezielle Probenahme von Prüfungsteilnehmern oder zusätzliche medizinische Untersuchungen oder Behandlungen vorgesehen sind oder die im Rahmen der Leistungsbewertungsprüfung durchgeführten In-vitro-Untersuchungen diagnostische oder therapeutische Konsequenzen für die Prüfungsteilnehmer haben können, gelten die §§ 47 bis 54 nicht für die Leistungsbewertungsprüfung von In-vitro-Diagnostika.

**§ 65a (1) MPG** Provisions of §§ 39, 40 (1, 3, 4, 5 and 7), 40a and 40b, 41 to 44 (2), and 46 to 64 also apply to all performance evaluations, unless determined otherwise in paragraph 2.

(2) if the clinical investigation is not associated with a specific sampling in type or amount from study participants or with additional medical diagnostic or therapeutic measures or if there are no therapeutic consequences for the study participants. §§ 47 to 54 do not apply to performance evaluations of and in-vitro-diagnostic.

This type of PE may also be conducted on samples from children (§ 51 MPG), pregnant women (§ 53 MPG), psychiatric patients (§ 52 MPG), persons performing military or non-military civil service (§ 49 MPG).

### 2.4. Studies according to § 40 (5) MPG

§ 40 (5) MPG can apply to medical devices of Directive 93/42/EEA and IVDs of Directive 98/79/EC but not for AIMDs according to Directive 90/385/EEA and to studies investigating:

- IVDs of all classes
- Class I medical devices
- Class IIa or IIb implantable medical devices
- Class IIa/IIb medical devices: use under 30 days and non-invasive
- Class IIa/IIb medical devices: use under 30 days and invasive
- Class IIa/IIb medical devices: use more than 30 days and non-invasive
- Class IIa/IIb medical devices: use more than 30 days and invasive
- Class III medical devices

Prerequisites for applicability of § 40 (5) MPG:

for the medical device:

- The medical device bears a CE mark according to § 15 MPG
- The medical device is used exclusively according to its conditions of use in the study (reference declaration of conformity /instructions for use)
- The study does not require additional therapeutic or diagnostic measures
- The medical device under investigation is not an AIMD

for IVDs:

- The IVD according to Directive 98/79/EG bears a CE mark according to § 15 MPG

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- The IVD is used exclusively according to its conditions of use in the performance evaluation (reference conformity declaration/instructions for use)

Note: The following changes to the intended purposes of a given medical device as referred to in the declaration of conformity are considered as incompatible with applicability of § 40 (5) MPG: other or additional indications, patient populations, or disease severities or disease stages; combinations with other medical devices; use of the device in the context of other or modified medical procedures; other user group (e.g., laypersons); other environmental conditions; and any other changes with regard to the intended purpose of the device.

**§ 40 (5) MPG** *Mit der klinischen Prüfung von Medizinprodukten gemäß der Richtlinie 93/42/EWG, die nach § 15 die CE-Kennzeichnung tragen, kann - sofern die klinische Prüfung keine andere Zweckbestimmung des Medizinprodukts als die in der Konformitätsbewertung vorgesehene zum Gegenstand hat und die klinische Prüfung keine zusätzlichen diagnostischen oder therapeutischen Maßnahmen notwendig macht - nach befürwortender Stellungnahme durch die zuständige Ethikkommission begonnen werden. Mit der Leistungsbewertungsprüfung von In-vitro-Diagnostika gemäß der Richtlinie 98/79/EG, die nach § 15 die CE-Kennzeichnung tragen, kann - sofern die Leistungsbewertungsprüfung keine andere Zweckbestimmung des In-vitro-Diagnostikums als die in der Konformitätsbewertung vorgesehene zum Gegenstand hat - nach befürwortender Stellungnahme durch die zuständige Ethikkommission begonnen werden. § 47 gilt nicht. (siehe Erläuterungen zum MPG BGBl I Nr. 143/2009)*

**§ 40 (5) MPG** Clinical investigations with medical devices in accordance with Directive 93/42/EEC that are authorized to bear the CE mark in accordance with § 15 may commence after the competent ethics committee has issued a favourable opinion, provided that the clinical investigation does not use the device for a purpose other than that referred to in the relevant conformity assessment procedure and that the clinical investigation does not require any additional diagnostic or therapeutic measures to be taken. Performance evaluations with in vitro diagnostics in accordance with Directive 98/79/EC that are authorized to bear the CE mark in accordance with § 15 may commence after the competent ethics committee has issued a favourable opinion, provided that the performance evaluation does not use the device for a purpose other than that referred to in the relevant conformity assessment procedure. § 47 shall not apply (see explanatory notes on MPG Federal Gazette I No. 143/2009).

There is no notification requirement to the BASG for § 40 (5) studies and the specific insurance requirements in accordance with § 47 do not apply. All other provisions regarding clinical investigations or performance evaluations, including any procedural provisions, remain applicable. The CI/PE may commence after the competent ethics committee has issued a favourable opinion. Legal reporting vigilance and SAE reporting requirements are applicable.

### Relaxed requirements:

- No insurance requirement for study participants (§47 MPG)
- No reporting obligation to the BASG

For an overview of reporting procedures in accordance with MPG § 40, see Annex II

## 3. SUBMISSION REQUIREMENTS

### 3.1. Electronic notification form

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The electronic application form for clinical investigations of medical devices / performance evaluations of IVDs can be accessed at the following link:

<https://applicationform.basg.gv.at/mpgform/>

In this system, the application form can be created, populated, stored locally and re-uploaded for changes. The minimum technical requirement for storing a XML-form is entering a protocol number.

Completing the application form does not lead to automatic submission to the BASG. For study notification, the completed application form must be submitted to the BASG as XML and PDF (together with the other required documents, see 3.2) on a data medium.

The signature of the applicant or sponsor on the PDF application form guarantees the correctness of data. The XML is used for further processing and transmission to the EUDAMED database. Therefore, the signatory is responsible for ensuring that the information in the PDF and XML forms are identical.

Only the applicant is entitled to enter data, therefore upon revisions and amendments an amended notification form (XML and PDF) needs to be submitted to the BASG by the applicant or sponsor.

### 3.2. Documents for valid submission

**§ 40 (1) MPG** Der Sponsor hat bei klinischen Prüfungen von Medizinprodukten das im Anhang 6 der Richtlinie 90/385/EWG, im Anhang VIII der Richtlinie 93/42/EWG, bei der Leistungsbewertungsprüfung von In-vitro-Diagnostika das im Anhang VIII der Richtlinie 98/79/EG angeführte Verfahren anzuwenden.

**§ 40 (4) MPG** Die Meldung an das Bundesamt für Sicherheit im Gesundheitswesen hat unter Einschluss der in den in Abs. 1 angeführten Anhängen genannten Erklärung zu erfolgen. Die dort angeführte Dokumentation ist auf Anforderung unverzüglich zur Verfügung zu stellen.

**§ 40 (1) MPG** In the case of clinical investigations with medical devices, the sponsor shall follow the procedure detailed in Annex 6 of Directive 90/385/EEC and in Annex VIII of Directive 93/42/EEC; in the case of performance evaluations with in vitro diagnostics, the sponsor shall follow the procedure detailed in Annex VIII of Directive 98/79/EC.

**§ 40 (4) MPG** The notification submitted to the Federal Office for Safety in Health Care shall include the statement detailed in the Annexes referred to in paragraph 1. The sponsor shall undertake to make available, immediately upon request, the documentation referred to in these Annexes.

A valid notification submitted to the BASG needs to contain the documents listed in Annex III (for a clinical investigation with a medical device) or Annex IV (for a performance evaluation with an IVD).

Upon request additional documents shall be made available to the BASG within a week.

### 3.3. Submitting a notification

The application form and dossier with a cover letter need to be submitted in electronic form on a data medium (e.g. CD). by postal delivery to the address below.

Documents requiring a signature should be signed electronically. If this is not possible, the signed and scanned original can be submitted.

#### Confirmation of receipt

An electronic confirmation of receipt will be issued for the following procedures: initial application, substantial and non-substantial amendment, notice of study termination, final study report. The respective e-mails will be sent to the contact given as study applicant in the application form. Keeping this information up-to-date lies in the interest and responsibility of the sponsor.



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### 3.4. Contact information of BASG

Please address your notification documents as well as any accompanying correspondence to:  
Federal Office for Safety in Health Care (BASG), Austrian Agency for Health and Food Safety (AGES)  
Institute Surveillance, Division Clinical Trials (CLTR)  
Traisengasse 5,  
1200 Vienna, Austria  
e-mail: [clinicaltrials@ages.at](mailto:clinicaltrials@ages.at)

### 3.5. Ethics committee opinion

In principle, the necessary application for an ethics opinion can be initiated before or simultaneously with the submission to the Agency. The submission date to the competent ethics committee(s) should be noted in the cover letter and form F\_I205\_Supplementary form for Clinical Investigations (Study Sites).

The notification of a study to the BASG will only be considered as complete and valid, once positive opinion of the competent ethics committee(s) has been obtained. In cases of ethics votes with obligations, these need to be fulfilled in order for the notification to be considered as valid. If available, a copy of the approval letter ('favourable opinion') by the ethics committee must accompany the notification documentation

In case of a negative ethics opinion the study will be rejected by the BASG by official notification. Alternatively, the applicant has the possibility to withdraw the study.

In the case of **multicentre** investigations, the competent ethics committee may decide to accept the opinion issued by another ethics committee involved in the same investigation. In this case, the ethics committee assessing the CI/PE must be provided with information regarding all additional investigators and with any documentation permitting assessment of the professional qualification and experience of the investigators, the available facilities, and the qualification of the supporting staff (§ 57 (2) MPG).

Further information on the application modalities to Austrian Ethics Committees can be found on the following website: [www.ethikkommissionen.at](http://www.ethikkommissionen.at)

## 4. ASSESSMENT BY THE COMPETENT AUTHORITY (BASG)

### 4.1. Confirmation of valid and complete notification

The sponsor has to submit to the BASG an adequate and complete notification. Upon receipt, the BASG will assess the documentation for formal completeness as quickly as possible.

If the notification of a CI/PE evaluation is found to be valid, the BASG will issue a written confirmation to this effect, which will also include the **reference number** assigned to the procedure. This reference number should be quoted in any future correspondence pertaining to that procedure.

For notifications in accordance with MPG § 40 (2), the 60-day assessment clock starts with the validation date on the BASG notification.

If the documentation submitted is not valid (i.e., if it is incomplete/incorrect), the applicant/sponsor will be asked to provide missing information and/or to correct deficiencies (improvement request, *Verbesserungsauftrag*). The

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notification submitted will not be considered valid until the deficiencies have been amended. Should the applicant/sponsor fail to submit the requested information, the BASG will reject the application.

### **4.2. Types of approval**

#### **4.2.1. Tacit approval/Non-interdiction**

Applies to initial applications and amendments according to § 40 (2) MPG: An application to the BASG is considered as approved, if a positive ethics opinion has been obtained AND no deficiencies have been raised during the 60 day assessment timeline by the BASG. The 60-day period starts on the validation date for initial applications and on the submission date for amendments.

#### **4.2.2. Official notification (“Bescheid”)**

An active approval by official notification earlier than the 60-day period is principally possible, if the quality of the dossier and available resources permit. Both paths to approval are equally valid.

#### **4.2.3. Notice**

A notification procedure applies to medical devices that do not fall under § 40 (2) and for performance evaluations of IVDs (§ 40 (3) and § 65a (2) MPG). The study can be initiated upon availability of a positive ethics opinion and confirmed valid notification to the BASG.

### **4.3. Refusal/Interdiction**

A study will be refused by official notification, if deficiencies have been raised during the assessment period, which have not been amended by the applicant within the set timeline. The notification will be issued on the basis of § 41 (4) MPG.

### **4.4. Assessment - Letters of deficiency**

The expert assessment follows the confirmation of valid submission. The BASG will evaluate the technical safety profile, any available medical and scientific information, any remaining risk weighed against the expected benefit of the clinical investigation (risk analysis), and the plausibility of the documents submitted.

Deficiencies may be detected or additional questions may be raised during expert assessment, resulting in additional document/information requests. These will be compiled in a letter of deficiencies, which will be sent to the applicant listed in the BASG-application form by e-mail.

The submission can be corrected once within an agreed timeframe. Prior to its expiry, this timeframe can be extended once by informal request by e-mail. Responses to letters of deficiencies have to be submitted in writing. Together with any documents requested or changed, they should be submitted in electronic form. Confirmation of resolved deficiencies will be issued by the BASG by e-mail. Subsequent approval by the BASG follows the paths outlined under 4.2.

If the deficiencies are not resolved and the applicant does not withdraw the study, the BASG will issue an official refusal as per 4.3

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### 5. AMENDMENTS TO THE CLINICAL INVESTIGATION PLAN (§ 40A MPG)

**§ 40a. (1) MPG** *Nach dem Beginn der klinischen Prüfung kann der Sponsor den Prüfplan ändern. Wenn die Änderung bedeutsam ist und sich insbesondere auf die Sicherheit der Prüfungsteilnehmer auswirken oder die wissenschaftliche Aussagekraft der klinischen Prüfung beeinflussen kann, hat der Sponsor bei klinischen Prüfungen gemäß § 40 Abs. 2 und 3 dem Bundesamt für Sicherheit im Gesundheitswesen und der zuständigen Ethikkommission den Inhalt der Änderung und sämtliche Gründe dafür zu melden. Bei klinischen Prüfungen nach § 40 Abs. 5 hat der Sponsor der zuständigen Ethikkommission den Inhalt der Änderung und sämtliche Gründe dafür zu melden.*

**§ 40a (1) MPG** After commencement of the clinical trial, the sponsor may make amendments to the clinical investigation plan. If, in the case of clinical investigations in accordance with § 40 (2) and (3), the amendment is substantial and likely to have an impact on the safety of the enrolled subjects or the scientific validity of the clinical investigation, the sponsor shall notify the BASG and the competent ethics committee of the content of, and the reasons for, this amendment. In the case of clinical investigations according to MPG § 40 (5), the sponsor shall notify the competent ethics committee of the content of, and the reasons for, these amendments.

If necessary, the clinical investigation plan can be amended after initiation of the clinical investigation. According to § 40a the reporting obligation to the BASG and the competent ethics committee is limited to substantial amendments (i.e., amendments involving changes that may have an impact on the safety of the enrolled subjects and/or the scientific validity of the clinical investigation).

The classification of the amendment as substantial or non-substantial according to Annex III (Classification of amendments) is the sponsor's responsibility and needs to be indicated in the submission.

The amendment application form F\_I200 and additional documentation should be submitted on a data carrier to the BASG. The date of receipt of the valid application is considered the starting date for assessment.

The submitted information should include a summary and justification of changes together with the updated documents. The changes should be clearly identifiable for the assessor (e.g., by compiling a synopsis or summary of changes, by tracking or colour-highlighting the changes).

#### **Changes to the application form**

The applicant needs upload the latest XML version validated by the BASG in the application system to make appropriate changes if needed. The amended application form as XML and PDF together with other required documents needs to be submitted on a data medium to the BASG.

### **5.1. Amendment types and approval**

#### **5.1.1. Amendments to § 40 (2) MPG studies**

##### **5.1.1.1. Tacit approval**

If the BASG does not issue a letter of deficiency within 35 days of receipt of the valid amendment notification, the amendment is considered as approved, provided that the concerned ethics committee has issued a positive opinion

##### **5.1.1.2. Confirmation**

The BASG can actively approve an amendment earlier than the foreseen timeframe.

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### 5.1.2. Amendments to § 40 (3) MPG studies

Amendments to CIs with devices that are not listed in 2.1 and PEs of IVDs are considered as approved upon valid notification to the BASG and a positive ethics opinion.

### 5.1.3. Urgent Amendments

Urgent amendments can be implemented without prior notification to the BASG. Examples for urgent amendments are the temporary suspension of an investigation for reasons of participant safety or the introduction of additional monitoring measures.

**§ 40a (5) MPG** *Unbeschadet der Abs. 1 bis 4 haben der Sponsor und der klinische Prüfer bei jeglichem neuen Umstand betreffend den Ablauf der Prüfung oder die Entwicklung des Medizinprodukts in klinischer Prüfung, der die Sicherheit der Prüfungsteilnehmer oder Anwender beeinträchtigen kann, die dringend gebotenen Sicherheitsmaßnahmen zu ergreifen, um die Prüfungsteilnehmer oder Anwender vor unmittelbarer Gefahr zu schützen. Sie haben bei klinischen Prüfungen nach § 40 Abs. 2 und 3 unverzüglich das Bundesamt für Sicherheit im Gesundheitswesen und die zuständige Ethikkommission über diese neuen Umstände und die getroffenen Maßnahmen zu informieren. Bei klinischen Prüfungen nach § 40 Abs. 5 haben sie unverzüglich die zuständige Ethikkommission über diese neuen Umstände und die getroffenen Maßnahmen zu informieren. Die Meldepflichten gemäß § 70 bleiben unberührt.*

**§ 40a (5) MPG** Without prejudice to the provisions of paragraphs 1 through 4, the sponsor and the investigator shall, in case of any new event relating to the conduct of the clinical investigation or the development of the medical device that may compromise the safety of enrolled subjects or users, take any appropriate urgent safety measures to protect the subjects or users against any immediate hazard. In the case of clinical investigations in accordance with § 40 (2) and (3) they shall, without delay, inform both the Federal Office for Safety in Health Care and the competent ethics committee of such new events and the measures taken. In the case of clinical investigations in accordance with § 40 (5), they shall inform the competent ethics committee of such new events and the measures taken. The notification requirements in accordance with § 70 shall remain unaffected.

### 5.1.4. Non-substantial amendments

Non-substantial amendments should be documented and brought to the BASG's attention with the next substantial amendment and do not have to be immediately notified to the BASG with two exceptions:

- Non-substantial changes that relate to the application form should be submitted to the BASG timely to ensure actuality of the database.
- Changes to the protocol required by the ethics committee that relate to the safety monitoring of the patients should be promptly submitted to the BASG.

If a separate notification is desired, the amendment notification form F\_I200 should be used.

## 6. FURTHER NOTIFICATION REQUIREMENTS DURING A CLINICAL INVESTIGATION

(§ 42 (8), § 70, § 61 (1), and § 64 (5) MPG)

### 6.1. Notification requirements for sponsors

#### 6.1.1. Serious Adverse Events (SAE) reporting

SAE criteria:

- The event is serious

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- The event is unwanted
- Attribution to the device under investigation is not required

The SAE reporting obligation applies to all clinical studies, independent of their reporting requirements. There is no legal exemption for studies according to § 40 (5). These reporting requirements also apply to studies that have been initiated prior to March 21<sup>st</sup> 2010. Further, reporting obligations according to § 70 MPG need to be considered (see 6.3. below)

**§ 42 (8) MPG** *Alle schwerwiegenden unerwünschten Ereignisse sind vom Sponsor vollständig zu registrieren und unverzüglich dem Bundesamt für Sicherheit im Gesundheitswesen und den zuständigen Behörden der anderen betroffenen Vertragsparteien des EWR, in denen die klinische Prüfung durchgeführt wird, zu melden.*

**§ 42 (8) MPG** The sponsor of a clinical investigation has to fully record all serious adverse events and notify them immediately to the Austrian Federal Office for Safety in Health Care and to all other competent authorities in those member states of the EEA in which the clinical investigation is being performed.

See Annex I for definitions. Examples:

- a. Where a medical condition is already established prior to the initiation of a clinical investigation and surgery has been scheduled to amend it, the definition of an adverse event according to MPG is not fulfilled and reporting to the BASG as SAE is not required. If the medical condition arises during the conduct of the clinical investigation, then SAE reporting to the BASG is required
- b. If a hospitalization preceded or was already planned prior to the initiation of a clinical investigation the definition of adverse event according to MPG is not fulfilled, no reporting as SAE is required. However, if unplanned hospitalization occurs during the conduct of the clinical investigation, SAE reporting to the BASG is required - whether or not causality has been established with the investigated device.

### 6.2. Notification requirements for investigators

**§ 61 MPG** *Der klinische Prüfer hat die Ethikkommission unverzüglich über alle schwerwiegenden Nebenwirkungen im Rahmen der klinischen Prüfung zu informieren. Die Meldepflichten des § 70 bleiben unberührt.*

The clinical investigator shall immediately report all serious adverse device effects occurring during a clinical investigation to the ethics committee. The notification requirements in accordance with § 70 remain unaffected.

**§ 64 (5) MPG** *Der klinische Prüfer hat den Sponsor über alle Medizinprodukte Nebenwirkungen und alle schwerwiegenden unerwünschten Ereignisse im Rahmen der klinischen Prüfung zu informieren.*

The clinical investigator shall inform the sponsor of any adverse device effects and serious adverse events occurring during a clinical investigation.

### 6.3. General notification requirements for investigators and sponsors

**§ 70 (1) MPG** *Angehörige eines gesetzlich geregelten Gesundheitsberufes, Gewerbeberechtigte, die berufsmäßig zum Betreiben oder zur Anwendung eines Medizinprodukts befugt sind, Leiter von einschlägigen Prüf-, Inspektions- und Zertifizierungsstellen und technische Sicherheitsbeauftragte von Krankenanstalten haben Informationen über Medizinprodukte im Hinblick auf Zwischenfälle, insbesondere*

1. *jede Fehlfunktion oder jede Änderung der Merkmale oder der Leistung eines Medizinprodukts sowie jeden*

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*Mangel in Bezug auf die Kennzeichnung oder die Gebrauchsanweisung, die geeignet sind, zum Tod oder zu einer schwerwiegenden Verschlechterung des Gesundheitszustandes eines Patienten, eines Anwenders oder eines Dritten zu führen oder die dazu geführt hat, oder*

- 2. bisher unbekannte schwerwiegende Nebenwirkungen oder das vermehrte Auftreten bekannter schwerwiegender Nebenwirkungen, oder*
- 3. bisher unbekannte wechselseitige Beeinflussungen, oder*
- 4. schwerwiegende Qualitätsmängel, die ihnen auf Grund ihrer beruflichen Tätigkeit bekanntgeworden sind, unverzüglich dem Bundesamt für Sicherheit im Gesundheitswesen zu melden sowie alle Beobachtungen und Daten mitzuteilen, die für die Medizinproduktesicherheit von Bedeutung sein können.*

**(2)** *Meldungen gemäß Abs. 1 haben bei Krankenanstalten, außer bei sonstiger Gefahr im Verzug, einheitlich im Wege des ärztlichen Leiters zu erfolgen.*

**(3)** *Alle natürlichen oder juristischen Personen, die Medizinprodukte im EWR erstmalig in Verkehr bringen und jene Betriebe, Einrichtungen oder Personen, die Medizinprodukte in Verkehr bringen, haben dem Bundesamt für Sicherheit im Gesundheitswesen unverzüglich Zwischenfälle gemäß Abs. 1 und darüber hinaus korrektive Maßnahmen, wie etwa*

- 1. jeden mit einem Medizinprodukt verbundenen technischen oder medizinischen Grund, der zum systematischen Rückruf von Medizinprodukten desselben Typs vom Markt durch den Hersteller geführt hat,*
- 2. die Ausstellung einer Maßnahmenempfehlung,*
- 3. die zusätzliche Überwachung oder Modifikation von Produkten,*
- 4. Modifikationen des Produktdesigns von Komponenten oder des Herstellungsprozesses, und*
- 5. Modifikationen der Kennzeichnung oder der Gebrauchsanweisung*

*mitzuteilen.*

**§ 70 (1)MPG** Members of a legally regulated health care profession, trade certificate holders licensed to operate or use a medical device, heads of pertinent test, inspection, and certification centres as well as technical safety officers of hospitals shall immediately notify the Federal Office for Safety in Health Care of any information regarding incidents in relation to medical devices that have come to their knowledge as a result of their professional activity, especially

1. any malfunction or change in the characteristics or performance of a medical device as well as any inadequacy in the labelling or the instructions for use which might lead to or has lead to the death or to a serious deterioration in the state of health of a patient, user, or third party or
2. any hitherto unknown serious adverse device effects or an increase in the occurrence of known serious adverse events or
3. any hitherto unknown interactions or
4. serious quality deficiencies

and to report any observations or data that may be of relevance for the safety of medical devices.

**(2)** For hospitals, notifications in accordance with paragraph 1 are to be submitted, without exception, through the medical director, unless there is danger in delay.

**(3)** All natural or legal persons first placing medical devices on the market within the EEA as well as companies, institutions, or persons placing medical devices on the market shall immediately report to the Federal Office for Safety in Health Care any incidents in accordance with paragraph 1, including any corrective measures taken, such as

1. any systematic recall of medical devices of the same type by the manufacturer, including the technical or medical reasons for the recall,

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| <ol style="list-style-type: none"><li>2. the issuance of recommendations on measures to be taken,</li><li>3. any additional surveillance measures or product modifications,</li><li>4. changes in the design of product components or in the manufacturing process, and</li><li>5. changes to the labelling or the instructions for use.</li></ol> |
|--|

For more information and downloadable notification forms, please see:

[www.basg.at/medizinprodukte/vigilanz-und-marktueberwachung/](http://www.basg.at/medizinprodukte/vigilanz-und-marktueberwachung/)

### 6.4. SAE notification forms for use in clinical investigations:

SAEs occurring in the course of clinical investigations are to be reported using the relevant forms (**F\_I209** or **F\_I287**), available for download on:

[www.basg.at/en/medical-devices/clinical-trials/](http://www.basg.at/en/medical-devices/clinical-trials/)

**F\_I209** — For SAEs occurring during a Clinical Investigation with a Medical Device at an Austrian study site

**F\_I287**—SAEs occurring during a Clinical Investigation with a Medical Device, EEA – line listing (tabular summary). All serious adverse events arising during a clinical investigation in Austria or at sites abroad need to be continually added to the line listing. Newly occurring SAEs or changes/additions to already reported SAEs need to be notified to the BASG and other competent authorities without delay.

Each SAE in the line listing needs to be associated with a status, i.e.

„a“ = added, new SAE/Complaint

„m“ = modified, new information for this SAE/Complaint

„u“ = unchanged, no new information for this SAE/Complaint (siehe Meldeformular F\_I287)

MEDDEV Guideline 2.7/3 "Clinical Investigation: serious adverse event reporting" and the related "SAE reporting" forms were published by the European Commission. SAE line listings may also be submitted in a format other than F\_I287 provided that:

- it contains all of the information required by form no. F\_287 e.g. SAE reporting form of MEDDEV Guideline 2.7/3 published by European Commission
- it contains a filter function (xls format),
- any changes compared to the previous version of the line listing are clearly marked or highlighted (new SAEs, changes to or follow-up information on previously reported SAEs),
- every SAE contained in the line listing can be unequivocally assigned to the clinical investigation during which it occurred by means of the BASG reference number.

Reporting can occur either electronically to [clinicaltrials@ages.at](mailto:clinicaltrials@ages.at) or per regular mail on a data carrier to the address listed earlier.

**Note:** Reporting obligations for clinical investigations according to MPG differ from those for clinical trials with medicinal products: According to the medicinal products act, (§ 41d AMG) all SAEs have to be reported by the investigator to the sponsor; however, there is no reporting obligation for SAEs to the BASG. SUSARs on the other hand, need to be reported and usually will be entered by the sponsor into the EudraVigilance (EV) database.

#### 6.4.1. Reporting timelines

Serious adverse events that result in immediate risk of death, serious injury or illness, need to be reported without delay, at the latest within 2 calendar days to the BASG, all other events within 7 calendar days. See also:

<http://ec.europa.eu/DocsRoom/documents/10330/attachments/1/translations/en/renditions/native>

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### 7. NOTIFICATION REQUIREMENTS AFTER TERMINATION OF THE CLINICAL INVESTIGATION (§ 44 MPG)

#### 7.1. End of study

The sponsor is obliged to report the end of study to the BASG. Two options are available:

1. Sole reporting of the global end of study without reporting the National end - In this case all reporting obligations remain until the global end of study
2. Informal reporting of the National end of study in addition to the subsequent reporting of the global end of study - In this case reporting obligations to the BASG will end with the National end of study with the exception of the provisions for the final study report. The National end of study is usually defined as the last visit of the last patient in Austria.

The end of a CI/PE should be notified and the final report submitted to the BASG using form F\_I207, which is available for download from [www.basg.at/en/medical-devices/clinical-trials/](http://www.basg.at/en/medical-devices/clinical-trials/)

#### Premature end:

A premature end to a CE/PE is to be reported by the sponsor to the BASG and other concerned National Agencies according to § 40 (6) MPG with a clear justification.

#### 7.2. Final study report

**§ 46 (1) MPG** Für jede klinische Prüfung ist ein schriftlicher Abschlussbericht zu erstellen, der von allen an der Prüfung beteiligten klinischen Prüfern zu unterzeichnen ist.

**§ 46 (1) MPG** For every clinical investigation, a written final report has to be prepared and signed by all investigators having participated in the clinical investigation.

The final report must contain a critical evaluation of the scientifically relevant data obtained during the clinical investigation (§ 46 (2) MPG) and will be reviewed by the BASG.

**§ 40 (6) MPG** Der Sponsor hat dem Bundesamt für Sicherheit im Gesundheitswesen und den zuständigen Behörden anderer betroffener Vertragsparteien des EWR den Abschluss der klinischen Prüfung, im Falle einer vorzeitigen Beendigung mit einer entsprechenden Begründung, zu melden. Diese Meldung hat auch an die zuständigen Behörden aller anderen Vertragsparteien des EWR und die Europäische Kommission zu erfolgen, wenn die vorzeitige Beendigung aus Sicherheitsgründen erfolgt. Der Abschlussbericht gemäß Anhang 7 Abschnitt 2.3.7 der Richtlinie 90/385/EWG bzw. Anhang X Abschnitt 2.3.7 der Richtlinie 93/42/EWG ist für das Bundesamt für Sicherheit im Gesundheitswesen und die zuständigen Behörden der anderen betroffenen Vertragsparteien des EWR bereitzuhalten.

**§ 40 (6) MPG** The sponsor shall notify the Federal Office for Safety in Health Care and the competent authorities of the other contracting parties to the EEA involved in the clinical investigation of the end or early termination thereof, providing justification in case of early termination. In the case of early termination of the clinical investigation on safety grounds, the declaration of the end of the investigation shall be notified to all contracting parties to the EEA and to the European Commission. The final report referred to in Annex 7 Section 2.3.7 of Directive 90/385/EEC and Annex X Section 2.3.7 of Directive 93/42/EEC shall be kept at the disposal of the Federal Office for Safety in Health Care and the competent authorities of the other contracting parties to the EEA participating in the clinical investigation.



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### **8. DRUG/DEVICE COMBINATION STUDIES IN ACCORDANCE WITH BOTH AMG AND MPG**

For combination studies (i.e., studies performed in accordance with both the Austrian Medicines Act (, AMG) and the MPG, both notification requirements must be fulfilled. Combination studies should be indicated as such in the Cover letter. A single notification of all documents in electronic form on data carrier is advised, a special fee applies (see 9.).

Substantial amendments to the clinical investigation or evaluation plan as well as adverse events and adverse drug reactions/adverse device effects have to be reported in accordance with the provisions of both the AMG and the MPG, with notifications to be submitted separately.

The guidance document for clinical trial applications in accordance with the Austrian Medicines Act (§ 40 AMG,) is available for download from [www.basg.at/en/medicines/before-authorisation/clinical-trials/](http://www.basg.at/en/medicines/before-authorisation/clinical-trials/)

### **9. FEES**

In accordance with the Fees Regulation issued by the Federal Office for Safety in Health Care pursuant to the Austrian Health and Food Safety Act (*Gesundheits- und Ernährungssicherheitsgesetz*, GESG) applications for a CI/PE are associated with a fee (see fee schedule in German at [www.basg.gv.at/en/about-us/fees/](http://www.basg.gv.at/en/about-us/fees/)).

If an application is withdrawn or rejected prior to validation, 10 percent of the applicable fee will be leveraged. Withdrawal after validation requires the payment of the full fee.

Combination studies: If the dossiers according to MPG and AMG are simultaneously to the BASG the fee will consist of the fee for the submission of an MPG study plus 35 percent of the fee for AMG trial submission. Combined trials need to be indicated as such in the cover letter.

Should the billing address differ from that of the applicant, this needs to be clearly indicated in the cover letter.

## **10.FREQUENT QUESTIONS**

### **10.1. Archiving obligations for Patient data**

No explicit legal provisions exist for clinical investigation with medical devices to regulate timelines for archiving patient data. Therefore reference is made to the "Kranken- und Kuranstaltengesetz" (KaKuG) and the „Wiener Krankenanstaltengesetz" (KAG). A clinical investigation is considered equal to a medical treatment and the requirements for archiving are therefore the same as for the general patient history.

According to § 10 (1) 3 KAKuG as amended and § 17 (2) KAG as amended hospitals need to archive patient histories for at least 30 years, outpatient clinics for at least 10 years in form of micro films or equal form in duplicate. X-ray pictures and other components of patient histories whose validity cannot be maintained for 30 years need to be archived for at least 10 years.

The requirements of the KAG do not apply to study participants that do not receive a medical treatment.

Further reference is made to the ISO guidance document EN ISO 14155 Clinical investigation of medical devices for human subjects -- Good clinical practice - provisions for archiving" When setting these requirements a risk analysis should be conducted with regards to reporting obligations associated with CE-marking and liability requirements.

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In addition, medical practitioners are obliged to archive notes and other conducive documentation according to paragraph 1 for at least 10 years according to § 51 (3) "Ärztegesetz" as amended. Conducive documentation can be considered as all documentation associated with the clinical investigation (including reports to the agency, final study reports). Therefore it is recommended to archive study documentation for at least 10 years.

### 10.2. Requirements for IT-servers

If data of the clinical study are stored electronically they need to be kept in validated archiving systems. An essential aspect of such a computerized system is that the data are protected against loss or change. Data integrity needs to be ensured. The requirements for computerized systems are laid out in the PIC/S Guidance 11-3 on Computerized Systems ([www.picscheme.org](http://www.picscheme.org)).

*Note:* EMA recommends use of this guidance for clinical trials with medicinal products and the BASG suggests to also use it as a reference for clinical investigations with medical devices.

### 10.3. Payment of investigational medical devices

**§ 63 (4) MPG (4)** *Der Sponsor hat Sorge dafür zu tragen, daß weder dem Prüfungsteilnehmer noch den österreichischen Sozialversicherungsträgern oder Dritten aus der Bereitstellung des für die klinische Prüfung bestimmten Medizinproduktes Kosten entstehen, es sei denn, daß*

- 1. mit dessen Einsatz ein primärer individueller Nutzen insofern verbunden ist, als es zur Abwehr einer gesundheitlichen Schädigung oder zur Behebung eines körperlichen Leidens dringend benötigt wird und gegenüber verfügbaren, bereits zulässig in Verkehr befindlichen Medizinprodukten eine wesentliche Steigerung der Erfolgchancen ernsthaft erwarten läßt,*
- 2. dem Sozialversicherungsträger oder Dritten Informationen über das verwendete Medizinprodukt und die klinische Prüfung zugänglich gemacht worden sind und*
- 3. Sozialversicherungsträger oder Dritte auf Grund dieser Unterlagen nach Beurteilung des Vorliegens der Voraussetzungen der Ziffern 1 und 2 einem Antrag auf Kostenübernahme zugestimmt haben.*

**§ 63 (4) MPG** It is the sponsor's responsibility to assure that no cost arises for the study participant or the Austrian Health Care System or third parties from providing the investigational medical device(s) for the conduct of the clinical study, unless the following situations present

1. Application/use of the medical device results in a primary individual benefit resulting from the prevention of health damage or the urgent need to treat bodily harm, and where significantly increased treatment success can reasonably be expected compared to currently available medicinal products
2. Information on the medical device to be used and the clinical study have been made accessible to the Health Care System or a third party and
3. the Health Care System or third party have agreed to carry the cost based on evaluation of requirements according to item 1 and 2

In principle, this paragraph also applies to medical devices that are already in routine use (i.e. as part of a clinical investigation according to § 40 (5)). In this case payment for the investigational medical device can be contractually agreed between the sponsor and the investigational site.

## 11. CONTACT

Should you have further questions on clinical studies with medical devices please check our homepage ([www.basg.gv.at](http://www.basg.gv.at)) or address them to:

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clinicaltrials@ages.at

### 12. REFERENCES

- Federal Office for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen, BASG)  
[www.basg.gv.at/medizinprodukte/klinische-pruefung-von-medizinprodukten/](http://www.basg.gv.at/medizinprodukte/klinische-pruefung-von-medizinprodukten/)
- Austrian Agency for Health and Food Safety (Agentur für Gesundheit und Ernährungssicherheit, AGES)  
[www.ages.at](http://www.ages.at)
- Federal Ministry of Health (Bundesministerium für Gesundheit, BMG)  
[www.bmg.gv.at](http://www.bmg.gv.at)
- European Commission – Legal framework  
[ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index\\_en.htm](http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/index_en.htm)
- European Commission – Legal framework – MEDDEVs  
[http://ec.europa.eu/growth/sectors/medical-devices/guidance/index\\_en.htm](http://ec.europa.eu/growth/sectors/medical-devices/guidance/index_en.htm)
- European Commission – List of harmonized standards  
<http://ec.europa.eu/growth/single-market/european-standards/>
- Forum of the Austrian Ethics Committees  
[www.ethikkommissionen.at/](http://www.ethikkommissionen.at/)
- International Conference on Harmonisation (ICH)  
[www.ich.org/home.html](http://www.ich.org/home.html)
- Legal Information System of the Republic of Austria (RIS), operated by the Austrian Federal Chancellery  
[www.ris.bka.gv.at/](http://www.ris.bka.gv.at/)
- Austrian Standards – Harmonized standards  
<http://austrianstandardsinstitute.com/>

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### 13. ANNEX I - SELECTED DEFINITIONS

#### Dir 93/42/EEC Art. 1 (2) "medical device"

means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

#### Dir 90/385/EEC Art. 1 b) "active medical device"...

means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

#### Dir 90/385/EEC Art. 1 c) "active implantable medical device"...

means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

#### Dir 93/42/EEC Art. 1 (2) c) "in vitro diagnostic medical device"...

means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures

Specimen receptacles are considered to be in vitro diagnostic medical devices.

Specimen receptacles are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination

#### Dir 93/42/EEC Art. 1 (2) g) "intended purpose"...

means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials

Note ad instructions for use: According to § 9 (6) MPG medical devices can only be dispensed to users or consumers, if the relevant information has been provided in the local language, e.g. the German language for Austria (Dir 93/42/EEC Annex I (13))

No further instructions are provided on the translation requirements of instructions for use in the Austrian medical device legislation. The information has to be complete and have to be provided in a way that they can be understood by the user/consumer. The safe and effective use of the medical device needs to be ensured. Translation by a certified translator is recommended and reference is made to DIN EN 15038

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Translation services - Service requirements. The "quality" of the translation can only be assured by peer review and therefore a translation service needs to encompass at minimum the translation and review by a person other than the translator

**§ 2 (17) MPG:** *"Nebenwirkungen" sind die bei einer bestimmungsgemäßen Verwendung eines Medizinproduktes auftretenden und damit in Zusammenhang stehenden unerwünschten Begleiterscheinungen.*

An **"adverse device effect"** (Nebenwirkung) is any undesirable clinical event occurring under and related to the normal conditions of use of a medical device, i.e., a device-related adverse event.

**§ 3 (16) MPG:** *Als schwerwiegend ist ein Ereignis oder eine Nebenwirkung im Sinne des § 2 Abs. 17 einzustufen, die tödlich oder lebensbedrohlich ist, zu bleibenden Schäden führt oder eine stationäre Behandlung oder eine Verlängerung des stationären Aufenthaltes erforderlich macht. Jedes unerwünschte Ereignis oder jede Medizinprodukte Nebenwirkung, die die Schädigung eines Feten, dessen Tod oder eine angeborene Fehlbildung verursacht, oder das Auftreten eines bösartigen Tumors sind in jedem Fall als schwerwiegend einzustufen.*

An **adverse event** or an **adverse device effect** in accordance with § 2 (17) is to be considered serious if it is fatal or life-threatening, causes permanent damage, or requires or prolongs hospitalization. Any adverse event or adverse device effect causing fetal damage, fetal death, or a congenital anomaly as well as any occurrence of a malignant tumour shall, without exception, be classified as serious.

**§ 3 (2) MPG „Klinische Prüfung“ (i.e. Clinical Investigation, CI)** *ist eine systematische Untersuchung eines Medizinproduktes, ausgenommen In-vitro-Diagnostika, an Prüfungsteilnehmern, mit dem Ziel,*

- 1. die Leistungsdaten des Medizinproduktes zu ermitteln oder zu überprüfen, ob die Leistungen des Medizinproduktes bei normalen Einsatzbedingungen den vom Hersteller oder sonstigen Sponsor angegebenen Leistungsdaten entsprechen*
- 2. etwaige bei normalen Einsatzbedingungen auftretende Nebenwirkungen nach Art, Schwere und Häufigkeit im Hinblick darauf zu ermitteln, ob diese unter Berücksichtigung der vorgegebenen Leistungen vertretbare Risiken darstellen oder*
- 3. Wirkungsmechanismen und geeignete klinische Einsatzgebiete des Medizinproduktes zu ermitteln, um damit die Sicherheit und Wirksamkeit des Medizinproduktes zu untersuchen.*

A Clinical trial is the systematic investigation of a medical device except IVDs on study participants with the goal of

1. evaluating the performance of a medical device or to verifying if the performance of the medical device in normal conditions of use conforms with those stated by the manufacturer or other sponsor
2. investigating adverse events according to type, severity and frequency under normal conditions of use and if those can be considered as acceptable risks in the context of the stated performance.
3. identifying the mechanisms of action and the suitable clinical use of a medical device to determine its safety and efficacy

**§ 3 (2) a „Leistungsbewertungsprüfung“ (i.e. performance evaluation, PE)** *ist eine systematische Untersuchung eines In-vitro-Diagnostikums in medizinischen Laboratorien oder sonstigen geeigneten Einrichtungen an Proben von Prüfungsteilnehmern, einschließlich Blut- und Gewebespenden, mit dem Ziel,*

- 1. die Leistungsdaten des In-vitro-Diagnostikums zu ermitteln oder zu überprüfen, ob die Leistungen des In-vitro-Diagnostikums bei normalen Einsatzbedingungen den vom Hersteller oder sonstigen Sponsor angegebenen Leistungsdaten entsprechen,*
- 2. etwaige bei normalen Einsatzbedingungen auftretende Risiken nach Art, Schwere und Häufigkeit im Hinblick darauf zu ermitteln, ob diese unter Berücksichtigung der vorgegebenen Leistungen vertretbare Risiken darstellen oder*

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3. *Nachweismöglichkeiten und geeignete medizinische Einsatzgebiete des In-vitro-Diagnostikums zu ermitteln, um damit die Sicherheit und Leistungsfähigkeit des In-vitro-Diagnostikums zu untersuchen.*

... is the systematic investigation of an in vitro diagnostic on samples of study participants, including blood and tissue samples in medical laboratories or other institutions with the goal of:

1. determining or verifying the performance of the in vitro diagnostic, or determining of the performance of the in vitro diagnostic conforms with the performance under normal conditions of use as stated by the manufacturer or other sponsor
2. investigating risks under normal conditions of use according to type, severity and frequency and if those can be considered as acceptable risks in the context of the stated performance or
3. determining the capacity and suitable clinical use of the in vitro diagnostic to determine the safety and performance of the in vitro diagnostic

**§ 3 (5) „Sponsor“** *ist jede natürliche oder juristische Person, welche die Verantwortung für die Planung, die Initiierung, die Durchführung und die Finanzierung einer klinischen Prüfung übernimmt. Der Sponsor muss in einer Vertragspartei des EWR niedergelassen sein.*

*Der klinische Prüfer hat die Pflichten und die Verantwortung des Sponsors zusätzlich zu übernehmen, wenn er eine Klinische Prüfung unabhängig vom Hersteller des Medizinproduktes und in voller Eigenverantwortung durchführt.*

Sponsor is a natural or legal person who takes the responsibility for the planning, initiation, conduct and financing of a clinical study. The sponsor has to reside in a signatory party of the EEC. The clinical investigator additionally has to take sponsor responsibility if he conducts the study in his full responsibility independently of the manufacturer of the medical device.

Note: § 3 (5) MPG does not specifically provide a definition for the legal representative, nevertheless the legal interpretation is in analogy to that of the medicinal product legislation (AMG):

**§ 2a (16) AMG „Sponsor“** *ist jede physische oder juristische Person, die die Verantwortung für die Planung, die Einleitung, die Betreuung und die Finanzierung einer klinischen Prüfung übernimmt.*

*Der Sponsor oder sein Bevollmächtigter müssen in einer Vertragspartei des Europäischen Wirtschaftsraumes niedergelassen sein. Der Prüfer hat die Pflichten und die Verantwortung des Sponsors zusätzlich zu übernehmen, wenn er eine Klinische Prüfung unabhängig vom Hersteller des Arzneimittels und in voller Eigenverantwortung durchführt.*

A sponsor is a natural or legal person who takes responsibility for the initiation, management and/or financing of a clinical trial;

The sponsor or his legal representative have to reside in a signatory party of the EEC. The clinical investigator additionally has to take sponsor responsibility if he conducts the study in his full responsibility independently of the manufacturer of the medicinal product

**§ 2 (9) MPG „Zweckbestimmung“ (i.e. Intended purpose)...**

*ist jene Verwendung, für die das Medizinprodukt nach Angaben des Herstellers in der Kennzeichnung, der Gebrauchsanweisung oder dem Werbematerial bestimmt ist. Die Festlegung der „Zweckbestimmung“ gemäß § 2 (9) MPG und der bestimmungsgemäßen Hauptwirkung des Produktes gemäß § 2 (1) MPG liegt in der Verantwortung des Herstellers.*

**intended purpose** means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials. The determination of the intended purpose according to § 2 (9) MPG and the intended primary mechanism of action according to § 2 (1) MPG are in the responsibility of the manufacturer.

Further definitions according to Annex IX Dir 93/42/EEC as amended (Classification of medical devices):

- Transient: Normally intended for continuous use for less than 60 minutes.
- Short term: Normally intended for continuous use for not more than 30 days.

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- Long term: Normally intended for continuous use for more than 30 days.

**Invasive device:** A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

**Body orifice:** Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma

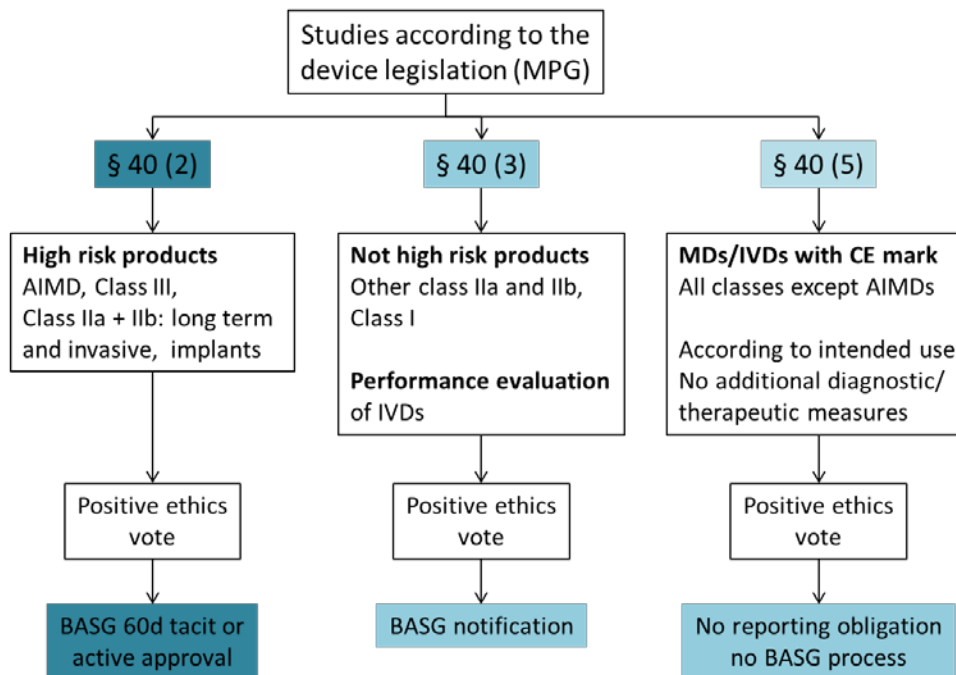
**Implantable device:** Any device which is intended:

- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye, by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

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### 14.ANNEX II - OVERVIEW OF NOTIFICATION REQUIREMENTS



**Notification requirements are based on the medical device classification** AIMD: Dir 90/385/EEC: Annex 6

- Medical devices according to risk classification: Dir 93/42/EEC: Annex VIII
- IVD: Dir 98/79/EC: Annex VIII

**Notification according to 40 (2) MPG – applicable to:**

- Dir 90/385/EEC: all AIMDs (no exceptions)
- Dir 93/42/EEC:
  - all class III medical devices
  - all implantable medical devices class IIa/IIb
  - class IIa/IIb medical devices:
    - for > 30 days continuous (long term) and invasive use (fully or partially implanted)

**Notification according to § 40 (3) MPG – applicable to:**

- Dir 98/79/EC: all IVDs
- Dir 93/42/EEC: all medical devices not mentioned in § 40 (2) or (5) MPG:
  - all class I medical devices
  - IIa/IIb medical devices used < 30 days and non invasive; < 30 days and invasive, or > 30 days and non invasive

**Notification according to § 40 (5) MPG – applicable to medical devices of Dir 93/42/EEC and IVDs of Dir 98/79/EC with the exception of AIMDs if**

- the medical device/IVD carries a CE mark
  - the medical device/IVD is used within its intended use (see conformity assessment)
  - the study protocol does not necessitate additional diagnostic or therapeutic measures
- no insurance requirement for study participants (§ 47 MPG)



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<b>Medical device/IVD classification</b>	<b>Notification procedure</b>
AIMD	§ 40 (2)
Implantat	§ 40 (2)
Class III	§ 40 (2)
Class IIa/IIb > 30d + invasive	§ 40 (2)
Class IIa/IIb < 30d + invasive	§ 40 (3)
Class IIa/IIb > 30d + non invasive	§ 40 (3)
Class IIa/IIb < 30d + non invasive	§ 40 (3)
Class I	§ 40 (3)
IVDs	§ 40 (3)

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### 15. ANNEX III: REQUIRED DOCUMENTS FOR THE NOTIFICATION OF A CLINICAL INVESTIGATION WITH A MEDICAL DEVICE

An adequate and complete notification (statement) submitted to the Federal Office for Safety in Health Care (BASG) consists of the following documents:	
Document	Notes
Completed "Notification of a Clinical Investigation with a medical device" form	PDF (signed electronically or scanned signed original) and XML
Clinical Investigation Plan	With version number and date; compiled according to EN ISO 14155
Investigator's Brochure	Summary of the literature, including an evaluation thereof; general description of the device and its components; description of the mechanism of action of the device, along with supporting scientific literature; manufacturer's instructions for use and installation, including possible risks, contraindications, and warnings; description of the intended clinical performance; description of the materials used in the device; summary and evaluation of the in vitro and/or ex vivo data relevant to the device, including preclinical data; summary of relevant previous clinical experience with the device and with other devices with similar features; a list of international standards the device complies with in full or in part; results of the risk analysis.
For CE-marked medical devices, German-language instructions for use	General description of the device and its intended use, including a description of the software necessary for the proper application of the medical device
Favourable opinion of the competent ethics committee(s)	"positive vote"
Patient Information and Informed Consent Form for subjects enrolled in the clinical investigation	In German, with version number and date
Confirmation of insurance coverage for the subjects enrolled in the clinical investigation	Personal injury insurance; see § 47 of the Austrian Medical Devices Act ( <i>Medizinproduktegesetz</i> , MPG) as amended  The number of subjects to be enrolled in the clinical investigation must correspond to the number stated in the insurance contract.  In addition to making out a personal injury insurance, the sponsor has to make sure that the investigator is covered by an adequate personal liability and legal costs insurance (see MPG § 48 as amended).
Written confirmation that the medical device complies with the essential requirements of the applicable Directive in all aspects except those that will be assessed in the clinical investigation	Directive 93/42/EEC Annex I Directive 90/385/EEC Annex 1

The following documents shall be kept and made available to the Federal Office for Safety in Health Care (BASG) immediately upon request or no later than 7 days thereafter.	
Document	Notes
Declaration of conformity of the manufacturer	
Certificate(s) of notified bodies	
Proof of qualification of the clinical investigator(s)	Current dated and signed curriculum vitae
Written agreements between the sponsor, monitor, and clinical investigator establishing each party's responsibilities	In accordance with MPG § 44 as amended
Case Report Forms (CRFs)	
Information on the construction and manufacture of the device, especially sterilisation	
Results of construction calculations, assessments, technical tests, etc.	e.g., results of biocompatibility tests in accordance with EN ISO 10993, results of the assessment of the electrical safety in accordance with the standards of the EN 60601 series
Results of the risk analysis	Risk analysis, risk minimisation measures See EN ISO 14971
List of standards applied in full or in part	
For products manufactured using tissues of animal origin, risk management measures aimed at reducing the risk of infection	See Directive 2003/32/EC, MEDDEV Guidelines of the European Commission
Data on tests performed to assess the safety, quality, and	See Directive 2000/70/EC or Directive 2001/104/EC as well as Directive

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benefit of substances or derivatives from human blood	2001/83/EC
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### ANNEX IV: REQUIRED DOCUMENTS FOR THE NOTIFICATION OF A PERFORMANCE EVALUATION OF AN IVD

**An adequate and complete notification (statement) submitted to the Federal Office for Safety in Health Care (BASG) consists of the following documents:**

Document	Notes
Completed "Notification of a Performance Evaluation with an In Vitro Diagnostic medical device" form	PDF (signed electronically or scanned signed original) and XML
Evaluation Plan	With version number and date Compiled according to ÖNORM EN 13612 Statement of objectives; scientific, technical, or medical rationale; methods; required samples and analyses, the performance criteria and requirements to be assessed, type and scope of the evaluation, number of products involved
Information necessary to understand the function and application of the device	General description of the device and its intended use, including a description of the software necessary for the proper application of the medical device
German-language instructions for use for CE-marked in vitro diagnostic medical devices	
Favourable opinion(s) of the competent ethics committee(s)	"positive vote"
Patient Information and Informed Consent Form for subjects	In German, with version number and date Except for performance evaluations in accordance with § 65a (2) of the Austrian Medical Devices Act ( <i>Medizinproduktegesetz, MPG</i> ) as amended
Confirmation of insurance coverage for the subjects enrolled in the performance evaluation	Personal injury insurance; see MPG § 47 as amended The number of subjects to be enrolled in the clinical investigation must correspond to the number stated in the insurance contract. Except for performance evaluations in accordance with MPG § 65a (2) as amended In addition to making out a personal injury insurance, the sponsor has to make sure that the investigator is covered by an adequate personal liability and legal costs insurance (see MPG § 48 as amended).
Written confirmation that the in vitro diagnostic medical device complies with the essential requirements of Directive 98/79/EC in all aspects except those that will be assessed in the performance evaluation	See Directive 98/79/EC Annex I

**The following documents shall be kept and made available to the Federal Office for Safety in Health Care (BASG) immediately upon request or no later than 7 days thereafter:**

Document	Notes
Declaration of conformity of the manufacturer	
Certificate(s) of notified bodies	
Proof of qualification of the coordinator of the performance evaluation	Current dated and signed curriculum vitae
Agreements between the sponsor, monitor, and clinical investigator establishing each party's responsibilities	In accordance with MPG § 44 as amended
Information on how the data obtained during the performance evaluation will be recorded	
Documentation on the construction and manufacture (manufacturing method, sterilisation, etc.)	
Results of assessments and technical tests	
Results of the risk analysis	Risk analysis, risk minimisation measures See EN ISO 14971
List of standards applied in full or in part	
Documentation on the safety of components of animal or human origin	See Directive 2003/32/EC, MEDDEV Guidelines of the European Commission

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### 16. ANNEX V: CLASSIFICATION OF AMENDMENTS

A change is considered substantial, if it relates to

- the safety or the physical or mental integrity of the study participants OR
- the change can impact on the scientific validity of the clinical study

The classification as substantial or non-substantial is the sponsor's responsibility and only substantial amendments need to be reported to the BASG.

Change	substantial	non-substantial
Title or short title of the investigation		<b>X</b>
Main objective	<b>X</b>	
Indication/main indication	<b>X</b>	
Study design: randomized, cross-over, parallel, blinded, double-blind, controlled	<b>X</b>	
Adding or modifying sub-studies	<b>X</b>	
Type of location: hospital, outpatient clinic, private practice	<b>X</b>	
Control groups: treatment/placebo groups; other medical devices, medicinal products, placebo, no treatment	<b>X</b>	
Study duration/ recruitment period		<b>X</b>
Study duration per study participant providing that treatment exposure, endpoints and safety monitoring remain unchanged		<b>X</b>
Number of study participants (cases for analysis)	<b>X</b>	
Number of study participants per site (unchanged total study participants)		<b>X</b>
Change of in-/exclusion criteria	<b>X</b>	
Stopping rules	<b>X</b>	
Reducing follow-up/control visits	<b>X</b>	
Investigator contacts		<b>X</b>
Applicant/Sponsor contacts		<b>X</b>
Contacts of the legal representative in Austria/EEA		<b>X</b>
Sponsor, legal representative, principal investigator	<b>X</b>	
Logistics (sample storage/transport)		<b>X</b>
Clinical research organization (CRO)/ Clinical research associate (CRA)		<b>X</b>
Addition of study site in Austria	<b>X</b>	
Termination of a study site in Austria		<b>X</b>
Adding/eliminating endpoints	<b>X</b>	
Withdrawal of independent data monitoring board (DSMB)	<b>X</b>	

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Change of case report forms/administrative changes		<b>X</b>
Development of the investigated device	<b>X</b>	
Name of the investigated device	<b>X</b>	
Classification of the investigated device	<b>X</b>	
Replacement of investigated device(s)	<b>X</b>	
Adding a CE mark	<b>X</b>	
Relevant accessory/ies to investigated device	<b>X</b>	
Software required for functioning of the investigated device	<b>X</b>	
Medicinal products used in supportive function to the investigated device	<b>X</b>	
Therapeutic/medical measures associated with the investigated device (type of therapy, medication), diagnostic tests, diagnostic measures	<b>X</b>	
Minor changes to the protocol		<b>X</b>
Correction of typos		<b>X</b>