Reset form

Form G1c

Notification of a serious adverse event in connection with the manufacture or use of tissues, tissue preparations, or stem cells pursuant to Section 63i AMG (German Medicinal Products Act)

to the Paul-Ehrlich-Institut, Unit Pharmacovigilance II, Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany

Please see: www.pei.de/gewebevigilanz for further information

Email: pharmakovigilanz2@pei.de
Phone: +49 06103 77-3117

Please do not fill out this field
PEI No.:

Fax.: +49 06103 77-1268

Reporting tissue establishment:

Street, number:

Postal/zip code: **City/Town:**

Phone: **Fax:**

Internal case number

Tissues / tissue preparations affected by the event

Type of tissue/tissue prep.	Single European Code/SEC (40 characters) / ID code	Date of procurement	Date of transplantation	Date when event occurred

Tissue establishment

Name: _ EU tissue establishment code: _

Authorisation of the tissue(s)/tissue preparation(s):

☐ Authorisation pursuant to Section § 20b and § 20c AMG ☐ Authorisation pursuant to § 21a (1) AMG ☐ Authorisation pursuant to § 25 (1) AMG

Characterisation of the event

Defect was identified outside the tissue establishment: Yes ☐

Affected Tissue/tissue preparation was distributed: Yes ☐

Multiple occurrence of event: Yes ☐

Internal risk analysis has assessed event as serious: Yes ☐

Reporting to the PEI is required only if at least one of the above-mentioned criteria applies.

Serious event which impairs the quality or safety of tissues/tissue preparations based on a deviation in the following processes:

☐ **Procurement** ☐ **Preparation** ☐ **Preservation**

☐ **Testing** ☐ **Processing** ☐ **Storage**

☐ **Distribution** ☐ **Transport**

☐ **Other:** _

Detailed description of the event (attach informal report if required)

_ _
_ _
_ _

Assessment

_ _
_ _

Measures implemented

_ _
_ _
_ _

Information on the person reporting the event:

Last Name: **First name:** **Phone No.:**

Post code/zip code: **City or town:** **Fax No:**

Email:

Signature: **Date:**

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