

**Technical details for**

- basic protection devices** (according to Annex 2 no. 6 RöV)
- high protection devices** (according to Annex 2 no. 2 RöV)
- full protection devices** (according to Annex 2 no. 3 RöV)
- school X-ray devices** (according to Annex 2 no. 4 RöV)

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To be submitted in duplicate to: Bundesamt für Strahlenschutz, Bauartzulassungen, Postfach 10 01 49, 38201 Salzgitter, Germany (contact: [bauartzulassung@bfs.de](mailto:bauartzulassung@bfs.de))

**PLEASE NOTE:** Details that are to be treated as a company secret or trade secret and are not meant to be reproduced in the approval document must be highlighted or marked accordingly.

**1. Applicant** (company, address, contact details including email and/or phone number)

	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor
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**2. Details on the appliance**

2.1 Type designation / trade name

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2.2 Manufacturer (company, address, if different from 1)

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- Technical details required for type approval procedures pursuant to RöV, Annex 2 no. 6 (basic protection devices), no. 2 (high protection devices), no. 3 (full protection devices), no. 4 (school X-ray devices) -

### 2.3 Purpose of use of the appliance

for non-medical purposes as

- basic protection device according to Annex 2 no. 6 RöV
- high protection device according to Annex 2 no. 2 RöV
- full protection device according to Annex 2 no. 3 RöV
- school X-ray device according to Annex 2 no. 4 RöV

Further information on use:

### 2.4 Maximum performance data of the X-ray tube

Rated (high) voltage	max.	kV
Long-term rated current	max.	mA
Tube power	max.	kW
Approved amount of electricity per hour *)	max.	mAs/h
Pulse duration *)		s
Pulse rate *)	per hour	n
Tube current *)	max.	mA

\*) Details required for X-ray flash tubes

### 2.5 Temporal variation of the tube current (please check where applicable):

- DC voltage generator
- Other (description): \_\_\_\_\_

### 2.6 Type description

Construction, operating principle and essential radiation protection features (cf. REMARKS p. 7)

- Copies and supporting documents enclosed (as specified in item 6.1)

- Technical details required for type approval procedures pursuant to RöV, Annex 2 no. 6 (basic protection devices), no. 2 (high protection devices), no. 3 (full protection devices), no. 4 (school X-ray devices) -

## 2.7 Description of the safety components of the appliance

Existing documents relating to safety systems, please check where applicable

(a detailed list of the documents shall be specified in item 6.4, cf. REMARKS p. 7)

- Description of the fundamental design and mode of operation of the safety systems
- Information on avoiding systematic errors (such as construction principles, choice of components, circuit structures, consideration of operational conditions, protection against internal and external interference, protection against loss of redundancy etc.)
- Information on avoiding future errors (such as avoiding loss of the safety function through single errors, error detection, blocking mechanism etc.)
- Information on organisational measures (if necessary) ensuring the safety function (in individual cases required for high protection devices and/or basic protection devices)
- Existing expert's reports with respect to the safety components (e.g. TÜV report)
- Complementary documents, e.g. source code for safety software, information on locking doors and service flaps etc.
- Other:

## 3. X-ray tube housing assembly (*X-ray tube and protective tube housing*)

### 3.1 Type designation / trade name

### 3.2 Manufacturer (company, address, if different from 2.2):

## 4. Protective tube housing

### 4.1 Type designation / trade name

### 4.2 Manufacturer (company, address, if different from 2.2)

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**5. X-ray tube** *(must be indicated even if the X-ray tube housing has been designated)*

**5.1** *Type designation / trade name*

**5.2** *Manufacturer (company, address, if different from 2.2)*

**5.3** *X-ray tube details*

e.g. model, design and material, nature and material of the anode and the exit window, angle of emergence

Supporting copies and documents enclosed as specified in item 6

**5.4** *Designation of further X-ray tubes to be used*

<b>Manufacturer</b> Companies, addresses, if different from 2.2	<b>Product names / types</b>	<b>Further details</b> (e.g. anode material, specific models etc.)





- Technical details required for type approval procedures pursuant to RöV, Annex 2 no. 6 (basic protection devices), no. 2 (high protection devices), no. 3 (full protection devices), no. 4 (school X-ray devices) -

**REMARKS on the requirements for basic protection devices, high protection devices, full protection devices and school X-ray devices pursuant to Annex 3 RöV**

Requirements	Basic protection devices	High protection devices	Full protection devices, school X-ray devices
<i>Local dose rate at a distance of 0.1 m from the touchable surface of the protective housing</i>	10µSv/h (maximum), even at a distance of 0.1m from the openings used for introducing and extracting the object of investigation	10µSv/h (maximum)	3µSv/h (maximum)
<i>Operation of the X-ray tube only when protective housing is completely closed</i>	Required, with the exception of the openings (see above) and/or continuous tube operation if the local dose rate inside the open protective housing does not exceed 10µSv/h.	Required, with the exception of continuous tube operation if the local dose rate inside the open protective housing does not exceed 10µSv/h or – if only reaching into the appliance is possible – the local dose rate in the accessible part of the interior does not exceed 250µSv/h.	Required, with the exception of continuous tube operation if the local dose rate inside the open protective housing does not exceed 3µSv/h.  Two independent safety components are required.
<i>Other</i>	Introducing and extracting the object of investigation must be performed via sample changer or conveyor and the dimensions of the openings must be fit for this purpose.		It must be ensured additionally in the case of school X-ray devices that the maximum operating conditions cannot be exceeded.

Further requirements of safety components are stipulated in the resolution of the “Laender committee X-ray Ordinance” (LA RöV) of March 28, 2002. An aggregate list can be found in the relevant PTB guideline (report DOS 49 of December 2005) (cf. item 2.7). For high protection and full protection devices as well as for school X-ray devices compliance with the requirements of the

- X-ray Ordinance,
- Technical guidelines,
- “Laender committee X-ray Ordinance” (LA RöV), and
- PTB guideline (DOS-49) must be demonstrated.

Existing external reports (e.g. TÜV report with respect to the safety components) shall be submitted with the application.

In the case of *full protection devices* and *school X-ray devices* the safety components must comply with safety category 3 (minimum requirement) as set out in the previously valid standard EN 954-1 (alignment with current standard EN ISO 13849-1 is in process). Furthermore the relevant regulations set out in DIN 54113-2 must be complied with. These requirements ensure that the failure of one safety component will not result in a failure of the entire safety system. The safety system must be able to recognize and display errors during operation or, at the latest, during the next start-up. It must be ensured that the radiation cannot be switched on again until the error has been resolved. Furthermore, the appliances have to be fitted with a time delay so that they cannot be opened before the acceleration voltage of the X-ray tube has fallen below 5kV.

In the case of *basic protection and high protection devices* a comparable level of safety can also be reached by introducing organisational radiation protection measures, such as regular controls conducted by competent operators or error detection by manually triggering the blocking mechanism.