Application for type approval pursuant to the German X-ray Ordinance (RöV)

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)

The personal data provided (such as name, adress, email adress) are processed by the Federal Office for Radiation Protection as part of the processing of your application. Further information, in particular regarding to your rights associated with the use of this data, is included in the Privacy Statement at www.bfs.de.

To be submitted in duplicate to: Bundesamt für Strahlenschutz, Bauartzulassungen, Postfach 10 01 49, 38201 Salzgitter, Germany (contact: 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)*

	☐ Manufacturer ☐ Distributor

2. Details on the appliance

2.1 Type designation / trade name

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

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)

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)

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

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

6. Documents required for type determination

6.1 Type drawings of the X-ray appliance

Technical drawings conforming to standard, which provide a precise overview of the design, dimensions and material of the appliance and the essential radiation protection components

Drawing number	Subject	Version / date

6.2 Type drawings of the X-ray tube housing assembly and/or protective tube housing

Technical drawings conforming to standard, which provide constructive details of the protective tube housing, e.g. dimensions, shielding material, nature and position of the shutter

Drawing number	Subject	Version / date

6.3 Type drawings of the X-ray tube

Technical drawings conforming to standard, which provide details on the internal design of the X-ray tube, in particular the dimension of and the material used for the anode, the position of the focal spot, special features etc.

Drawing number	Subject	Version / date

6.4 Documents relating to the safety components of the appliance

Design drawings, block diagrams or circuit diagrams which provide a precise and complete overview of the function and operating principle of the safety systems, allowing for a safety assessment, and (if possible) data sheets for the components or circuits used, source software, TÜV report

Documentation number / data medium	**Documentation name / subject**	**Version / date**

6.5 Further application documents, existing certificates

in addition, if available, drawings and documents in electronic form

Documentation number / data medium	**Documentation name / subject**	**Version / date**

6.6 Operating instructions

☐ Operating instructions in German language are available

Title: _____

No. _____ Published as of_____

☐ Documents and/or copies enclosed

☐ Operating instructions in German language will be filed later

Further information:

_____ _____

Date Signature and company stamp

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
Local dose rate at a distance of 0.1 m from the touchable surface of the protective housing	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)
Operation of the X-ray tube only when protective housing is completely closed	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.
Other	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.