

**Technical details for veterinary X-ray equipment
(according to Annex 1 RöV)**

unless such equipment is first placed on the market according to the regulations of the German Medical Products Law

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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)

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 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. X-ray tube housing assembly (X-ray tube and protective tube housing)

2.1 Type designation / trade name

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2.2 Manufacturer (company, address if different from 1)

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2.3 Purpose of use of the X-ray tube housing assembly

Employed in veterinary X-ray equipment for <input type="checkbox"/> X-ray diagnostic <input type="checkbox"/> X-ray therapy Other types of employment: _____
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- Technical details required for a type approval procedure pursuant to the German X-ray Ordinance (RöV), Annex 1 (Veterinary X-ray equipment) -

3. Protective tube housing

3.1 Type designation / trade name

3.2 Manufacturer of the protective tube housing (if different from 2.2)

4. X-ray tube

4.1 Type designation / trade name

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

4.3 X-ray tube details

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

Supporting documents and copies enclosed

4.4 Designation of further X-ray tubes to be used

Manufacturer companies, addresses, if different from 4.2	Type designation / trade name	Further details (e.g. anode material, specific models etc.)

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5. Construction and operation of the X-ray tube housing assembly

5.1 Maximum performance data

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

5.2 Temporal variation of the tube current (please check where applicable)

DC voltage generator

Other (description): _____

5.3 Type description

Main components of the appliance and their function with respect to the essential radiation protection features (dimensions, design, material), existing safety components, reference to technical guidelines (if applicable)

Supporting documents enclosed

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6. Documents required for type determination

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

Technical drawings conforming to standard, which provide a precise and complete overview of the design, dimensions and material of the appliance and the radiation protection components (e.g. shutter, screening etc.)

Drawing number	Subject	Version / date

6.2 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

6.3 Further application documents, existing certificates

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

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

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6.4 *Operating instructions*

<p><input type="checkbox"/> The X-ray tube housing assembly is operated independently; operating instructions in German language are enclosed indicating the essential radiation protection features.</p> <p>Title: _____</p> <p>No. _____ Published as of _____</p> <p><input type="checkbox"/> The X-ray tube housing assembly is intended for integration into X-ray appliances, remarks:</p> <p>_____</p> <p><input type="checkbox"/> Documents and/or copies enclosed</p> <p><input type="checkbox"/> Operating instructions in German language will be filed later</p> <p>Further information:</p>
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Date

Signature and company stamp