Quality management system

Please describe how your quality management system (QMS) takes care of the information below, refer to applicable routine or method in your QMS, as well as person or function responsible. For the initial assessment to be approved, it is necessary for your QMS to fulfil requirements equal to those in ISO 9001:2015.

If your answer doesn't fit in the box, please attach a separate document and reference in the box.

General information

1 Do you manufacture your product in-house or is manufacturing/assembly outsourced?

Description
Reference in QMS and responsibility

Equipment & measurement/testing

2 Describe maintenance and management of deviations in regard of production facilities and tools

Description
Reference in QMS and responsibility

3 Describe maintenance and calibration of in-house equipment

Description
Reference in QMS and responsibility

4 Describe outsourced measurement/testing in regard of requirements and periodic assessment

Description
Reference in QMS and responsibility

Swedish Transport Agency
Road and Rail Department
Box 267, SE-781 23 Borlänge, Sweden
Office address
Jussi Björlings väg 19, Borlänge

transportstyrelsen.se
vag@transportstyrelsen.se

Telephone +46 771 503 503
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5 Describe analysis of results, documentation and management of deviances in regard of measurement/testing

Description
Reference in QMS and responsibility

Production/product

6 Describe the production process

Description
Reference in QMS and responsibility

7 Describe control and measurement routines in the production process

Description
Reference in QMS and responsibility

8 Describe control and measurement routines related to the product

Description
Reference in QMS and responsibility

9 Describe traceability for the process and product

Description.
Reference in QMS and responsibility

10 Describe the process for non-conforming products

Description
Reference in QMS and responsibility

11 Describe your constant awareness of statutory and regulatory requirements

Description
Reference in QMS and responsibility

Conformity of Production (CoP)

As manufacturer you are responsible to the Swedish Transport Agency for all aspects of the type-approval or authorisation process and for ensuring conformity of production, regardless of whether you are directly involved in all stages of production or not.

Conformity of production means that the manufacturer have adequate arrangements to ensure that products conform with the approved type.

Please describe information related to that commitment in the fields below and
note that routines under 13-18 are mandatory to attach.

12 Describe the requirements in the regulation for which you apply for (Conformity of Productions criteria's)

Description
Reference in QMS and responsibility

13 Describe how samples are taken for tests

Description
Reference in QMS and responsibility
Mandatory appendix - enter name/no:

14 Describe the implementation of the CoP testing based on the requirements of the regulation, i.e. a control plan. If there are no specified requirements in regulation – what test are carried out?

Description
Reference in QMS and responsibility
Mandatory appendix - enter name/no:

15 Describe how you analyze the result of the mentioned tests above

Description

Reference in QMS and responsibility
Mandatory appendix - enter name/no:

16 Describe how you document the results of the tests mentioned above

Description
Reference in QMS and responsibility
Mandatory appendix - enter name/no:

17 Describe your routine for contacting the Swedish Transport Agency in the event of non-compliance with the type approved product

Description
Reference in QMS and responsibility
Mandatory appendix - enter name/no:

18 Describe your routine for contacting the Swedish Transport Agency in the event of changes that may affect your type approval

Description
Reference in QMS and responsibility
Mandatory appendix - enter name/no:

Send your application to

Transportstyrelsen
Väg och järnväg
Box 267
781 23 Borlänge

Sweden

Or e-mail to
cop@transportstyrelsen.se – **We prefer that you apply by e-mail**