

ANNEX X

CONFORMITY ASSESSMENT BASED ON TYPE-EXAMINATION

6. Administrative provisions

The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, its authorised representative shall, for a period ending no sooner than 10 years, after the last device has been placed on the market, keep at the disposal of the competent authorities:

- the documentation referred to in the second indent of Section 2,
- information on the changes referred to in Section 5,
- copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements.

Section 7 of Annex IX shall apply.