BABT 725

A Guide to the TUV SUD BABT Implementation of Annex III Module B of Radio Equipment Directive 2014/53/EU – EU Type Examination

Issue 11

Foreword

This guide explains the TUV SUD BABT Implementation of Annex III Module B of Radio Equipment Directive 2014/53/EU – EU Type Examination.

The scheme enables a manufacturer of product within the scope of the Radio Equipment Directive to affix a CE mark after satisfying the requirements of Annex III Module B of the Directive.

The formal requirements of the scheme are set out in the link to TUV SUD BABT Testing and Certification Regulations.

All publications are available from: http://www.tuv-sud.co.uk/babt

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1. Introduction

1.1 Scope

This guide explains the TUV SUD BABT Implementation of Annex III Module B of Radio Equipment Directive (RED) 2014/53/EU.

1.2 Overview

The TUV SUD BABT implementation of Annex III Module B operates under the TUV SUD BABT Certification Regulations.

Where the Technical Documentation supplied by the applicant demonstrates the required RED Annex III compliance, the formal output from TUV SUD BABT is an EU RED Type Examination Certificate.

2. Making an Application

2.1 Who to Apply To

The application should normally be made to your local TUV SUD office. If you do not know your local office, you may apply to TUV SUD Product Service (certification@tuv-sud.co.uk) at the same postal address as TUV SUD BABT (refer to the foreword).

The Application must be made using form BABT 500 and include sufficient information to determine whether the product falls within the Scope for TUV SUD BABT Certification.

Normally, the Application should be made in electronic format.

2.2 Who Can Apply

Applications can be made by or on behalf of both manufacturers and authorised representatives who supply radio equipment. The person making the application should be a duly authorised signatory of the applicant and may not be an agent or TUV SUD employee.

Optionally, the applicant may in addition authorise TUV SUD BABT to liaise with another party (e.g. a TUV SUD company/agent/consultant) acting on behalf of the applicant in matters relating to the application.

> TUV SUD BABT will require evidence that the representative or consulting agency is authorised by the applicant company to act on their behalf and there is a section of the application form for this purpose.
>
> If you wish to use your Authorised Representative to act on your behalf or hold the Type Examination Certificate, we will require a copy of your Authorised Representative Mandate.

2.3 Types of Application

The application should be made for Annex III Module B Type Examination on the BABT 500 application form.

You should indicate the Essential Requirements you require TUV SUD BABT to include within the assessment (i.e. Articles 3.1(a), (b), 3.2, 3.3 of the RED) (BABT 500 Section B refers),

You should also indicate whether this is an original submission / product variant submission or product modification submission for which TUV SUD BABT has already issued a Type Examination Certificate. This may include extending the scope of the certification to include further Essential Requirements. For modifications or product variant applications the details of the original product RED Type Examination Certificate number should be included in the BABT 500 application form.

Applications may cover either one product or a set of related products having significant design similarities.

> Products which are identical apart from product naming and cosmetic differences items may be included with the original application. Alternatively, separate applications may be made

Variant products or products within the same family with differing features but where there are significant design similarities may be submitted on the same application. However, information demonstrating their similarity will be required and additional testing/test results may be required for technical aspects which differ between models.

Variant products or products within the same family on the same application are generally only considered to be acceptable as sub-equipped / depopulated products which have substantial areas of circuitry and software in common.

Branded Products submitted by a different organisation from the original Type Examination Certificate holder must make a separate application together with authorisation from the original certificate holder.

2.4 Information Required for an Application

The following information should be supplied as appropriate as a part of the application. Entries for this information are included in form BABT 500.

2.4.1 BABT 500 Section A, Contact Details -

- Main contact name and address
  Details of the authorised signatory within the company applying for the certification and responsible for the certification request and order. This named person may not be an agent.
- A different company name or address (to be included with supporting information)
  where you wish the company name or address to appear on the certificate to differ from that of the primary contact (e.g. where you wish the Company HQ to be on certificates). This should be accompanied with details of the relationship between the contact and the supplied address/company.
- Please indicate in the drop-down box if the company name is the Registered name of the Company. Where the Registered company name is different from the name you wish to be included on the Certificate please provide details of the formal Registered company name with the application.
- An Agent/Consultant name and address (to be included with supporting information)
  Where you have used an agent/consultant to assist or submit the application, e.g. if you are submitting through TUV SUD BABT ICM or a TUV PS company this should be their details).

2.4.2 BABT 500 Section B, Your Certification Requirements –

- Certification requirements (see section 2.3 Types of Application of this document)

2.4.3 BABT 500 Section C, Product Details -

- Product name(s)/model(s)
  must be clearly stated as this will appear on the certificate and serve as a prime identifier of the certified product(s).
- Technical Documentation overall document file identity
  must be included as this also will appear on the certificate. Where there is no overall identity then the Document number of the Index (or Contents listing) should be provided. This Technical Documentation file identity is referenced on the RED Type Examination Certificate.
- Brief Description of the Product including its intended purpose

  This should be in sufficient detail to enable TUV SUD BABT to understand the product and ensure it is within the Scope of the appointment and legally able to be sold (e.g. GSM repeaters may only be approved where they are intended for use by Network Operators)
- Product Type
  Please list the product type and any additional description. The standard product types are listed in Annex B of this document; where none of this match your product you may submit a suitable description. Note to assist you the form includes a drop-down menu of the most popular product types.
- Additional Information
  It is also helpful (but not mandated) if you provide a brief description of the product to assist in understanding the product purpose.

- Radio interfaces
  Please list the type and frequency bands used for all radio interfaces subject to the certification. It is acceptable for this to be in a separate document providing this is easy to understand and in a similar format. This section is continued in Annex A of the BABT 500 application form.
- An explanation of the relationship between models
  Where you have submitted technical documentation covering more than one model.
  In particular whether one can be derived from another by sub-equipping/ depopulation and whether they have substantial areas of circuitry or software in common.
- For OEM products
  Where your product is an OEM product for which TUV SUD BABT have already issued a Type Examination Certificate please provide details of any differences and a letter from the holder of the original certificate granting you access to their results.

2.4.3 BABT 500 Section D Agreement -

- A signed declaration for statements included on the BABT 500 form including that the same application has not been lodged with any other notified body.

- The application should also be accompanied with supporting technical documentation as detailed in the later sections of this document. An initial application can be made to obtain the reference for the TUV SUD BABT RED Type Examination certificate number providing the BABT 500 application form is accompanied with limited technical documentation such as the user manual and technical specification.

2.5 Technical Documentation

2.5.1 General

The completed BABT 500 application form should be accompanied by technical documentation.

A checklist for the required technical documentation is in Annex B of the BABT 500 application form which should be considered for completion by the applicant. Whilst we would not reject applications without this being completed we would recommend that this is completed by new applicants to the scheme. The simple fact of missing technical documentation has the potential to delay RED Annex III type examinations.

The technical documentation must be sent via electronic media (preferably by TUV SUD Drop-off or via e-mail attachments although ftp can be used). Documents should be in Word. Excel, Adobe PDF, or images in JPEG formats. Where you wish to use other formats, or employ encoding please contact TUV SUD BABT prior to submission to ensure we will have ready access to the files. Zipped files should be in WinZip format.

All documentation should be readily identifiable with either revision indication or an issue date. Multiple paged documents should have indications, page numbers or listed sections to ensure they are complete.

2.5.2 Technical Documentation Contents

Since each set of technical documentation is unique, there is no fixed structure or mandated set of contents. However, as an example submitted technical documentation should contain the following information.

- Index or Content list
- Description of the apparatus
- A statement of all intended operating conditions and, for the essential requirement of Article 3(1)(a) [Health & Safety], the statement shall take into account the reasonably foreseeable conditions
- Procedures to ensure compliance, including an adequate analysis and assessment of the risks
- Test Data
- User Instructions
- An explanation of the compliance with the requirement of Article 10(2) and relevant packaging details where Article 10(10) is applicable.

An expanded list with details of the contents is included for information in Annex A of this document.

2.6 Progressing the Application

When TUV SUD BABT has received your application and evaluated the initial information, we will:

- inform you of the TUV SUD BABT reference number assigned to your application. This number should be quoted in all further correspondence.
- advise you of any obvious omissions of items required for assessment (e.g. Test Reports)

When TUV SUD BABT has received all the required items the application will be allocated to a certification engineer for formal review.

2.7 Completion of Annex III Module B Process

2.7.1 Assessment Process

TUV SUD BABT reviews the supplied Technical Documentation for completeness, consistency and whether it demonstrates the product will be compliant with the requirements of the relevant articles of the RED required by the application.

If during the assessment the Engineer concludes that

- Required documentation is omitted; or
- The technical documentation includes unexplained inconsistencies; or
- Documentation is incorrect or incomplete; or
- Test results / reports are inconsistent or omitted; or
- Test results / reports do not demonstrate compliance to the essential requirement being assessed then the reviewing Engineer will contact the main contact with details of the concerns and seek a suitable response.

Where information is missing from an application or the reviewing engineer raises a query, further work on that application will be placed on hold and will only be resumed after receiving a response.

Inconsistent or Omitted test results

If during the assessment TUV SUD BABT concludes that additional testing is required, then you may either:

- request TUV SUD BABT decline to provide a Type Examination Certificate citing the absent or inconsistent results; or
- place the assessment on hold and obtain the additional required tests results.

Where the testing option is taken, test reports should consider the requirements of BABT 766 and Annex A6 of this document.

Once the required testing has been performed the test report should be sent to TUV SUD BABT and the Assessment resumed.

2.7.2 Assessment Outcome

After assessment of an Annex III Module B application and supporting documentation:

- if the Technical Documentation demonstrates compliance with the requested essential requirements of the Directive, TUV SUD BABT will issue a Type Examination Certificate confirming compliance;

Certificate

Certificates are issued in the name of the Applicant Company which is referred to as the holder. Certificates and their associated Annex also include:

- The address of the holder (or an alternate address where identified within the application)
- The product identity(ies) (including any variants/models)
- The reference to the Technical Documentation presented to TUV SUD BABT
- The RED Essential Requirements covered by the Certificate
- Information related to the interface type(s)
- The Standards used within the Technical Documentation
- Test Reports used in the Technical Documentation
- References to important Technical Documentation including the risk assessment
- Other data necessary for identification of the product, and any conditions for its validity.

The Certificate only relates to the inspected Technical Documentation.

Use of Registered Trade Names on Certificates

Where you wish to use a Registered Trade name associated with your product for which you are not the registered Name owner (e.g. Bluetooth®), you should ensure you have met all the criteria from the owner to make use of the Name. While TUV SUD BABT perform no independent check over your right to make use of the name we will revoke any Certificate where we are advised by a Trade name owner that you have infringed their conditions of use.

2.7.3 Resulting Actions

Where you obtain a Type Examination Certificate from TUV SUD BABT then:

- Where the certificate covers all the relevant requirements of article 3 of the RED you should draw up a Declaration of Conformity to the RED. An example of Declaration of Conformity content requirements can be found in Annex C of this guide);
- Where the certificate does not cover all the relevant requirements of article 3 of the RED, e.g. for an Article 3.2 Radio only assessment, you should review your technical documentation for the remaining essential requirements and only draw up a Declaration of Conformity to the RED when you are satisfied the technical documentation, as a whole, demonstrates compliance with all the relevant requirements of article 17 of the RED;
- When you have met all the requirements of all directives applicable to your product then you may mark your product with the CE mark. Refer to the next section of this guide for more details.

The issuing of an unfavourable certification decision completes the processing of the application from the TUV SUD BABT viewpoint.

It is then your choice whether to

- rectify the non-compliances and apply for another Type Examination Certificate; or
- rectify the non-compliances and follow another the RED Annex as appropriate to your equipment; or
- develop a reasoned justification for compliance with the RED, notwithstanding the identified non-compliances, for incorporation in the technical documentation, and follow the process for a favourable certification decision as described above.

You are entitled to make a formal appeal if you believe that you have been unjustly denied a certificate. In all cases, the decision of the appeals panel is final. Full details of the appeals procedure are given in the Certification Regulations.

2.7.4 Records

TUV SUD BABT maintains records of all the details on a certificate; of each submission and the resulting evaluation for 10 years after the last significant file activity.

During the technical documentation assessment, TUV SUD BABT draws up an evaluation report to record the assessment activities and outcomes. Apart from our obligations to the EU Commission and EU member states, we will release the content of that report, in full or in part, only with the agreement of the certificate holder.

TUV SUD BABT is required upon request to inform the UK Government Department for Business Innovation & Skills (DBIS), our notifying authority, of Type Examination Certificates which have been issued, withdrawn, refused, suspended or otherwise restricted.

TUV SUD BABT is required to inform the other RED notified bodies about Type Examination Certificates and their modifications which we been refused, withdrawn, suspended or otherwise restricted, and, upon request, about certificates and their modifications which we have issued.

TUV SUD BABT is required to inform the EU Member States of Type Examination Certificates and their modifications we have issued in those cases where the appropriate Official Journal listed harmonised standards have not been applied or not been fully applied. The Member States, the European Commission and the other RED notified bodies may, on request, obtain a copy of the EU-type examination certificates and their modifications. On request, the EU Member States and the Commission may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

You are required to maintain the records defined Annex V of the Directive for 10 years after the radio equipment has been placed on the market.

3. Intended Use

You are required to provide information with the product describing the networks with which the equipment is intended to connect and the radio frequencies it is intended to use. Where the radio frequency is not harmonised, this must include the countries in which the equipment is intended for use.

The stated intended use should be consistent with the technical documentation and RED Declaration of Conformity.

4. Registration of Certain Categories of Radio Equipment

The European Commission may specify that certain categories of radio equipment require registration within a central system that they operate. Some or all the technical documentation may need to be provided by the manufacturer. The European Commission will allocate a registration number to the registered radio equipment for affixing to the equipment.

The registration requirements will be defined by the European Commission for implementation from 12 June 2018.

5. Keeping your Technical Documentation up to Date

5.1 General

During the lifetime of a certified product, TUV SUD BABT understands that it is likely that you will want to make a few changes.

It is your responsibility to ensure that after each change the technical documentation, the Type Examination Certificate and Declaration of Conformity remain valid.

The RED requires the Declaration of Conformity to be continuously updated. A new Declaration of Conformity should be issued whenever compliance is re-established

Review each change: Whilst not all changes will be significant to compliance with the RED each change, however small, must be considered for its potential effects and their relevance to the conformance to the relevant standards.

All modifications to the certified product that may affect its conformity with the essential requirements of the RED or the conditions for validity of the certificate require approval by TUV SUD BABT.

“The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the radio equipment with the essential requirements of this Directive or the conditions for validity of that certificate.” RED Annex III (7) refers.

Type Examination Certificates are issued with a renewal date. This renewal date is 5 years from the issue of the

Certificate and is updated for each certificate issue.

Until the renewal date, TUV SUD BABT will inform certificate holders of changes to the Official Journal standards list that affect the conformity of certified products. Certificate holders may apply to TUV SUD for renewal of their certificate. However, the certificate remains valid after the renewal date.

5.2 Administrative Changes

Where TUV SUD BABT have issued a Type Examination Certificate and details on the certificate unrelated to compliance with the RED require change (e.g. Company address, Product name) then you may apply to TUV SUD BABT for an updated Certificate based upon the original assessment for an administrative change.

5.3 Product Changes

Where a change to a certified product has occurred that may affect its conformity with the essential requirements of the RED or the conditions for validity of the certificate, you should apply to TUV SUD BABT with details of the change and updated technical documentation. Typically, the details required are: certificate number, description of the modification, new/updated test reports and new/updated supporting documentation.

Alternatively, you may either apply to TUV SUD BABT for a completely new assessment or progress the change through an appropriate RED conformity assessment procedure.

When a Type Examination Certificate and/or its annex is changed, the new issue replaces the previous certification; and invalidates the previous certificate for future supply to the market.

5.4 Changes to the State of the Art

TUV SUD BABT is required to keep itself appraised of any changes in the generally acknowledged state of the art and be aware of changes which may affect the compliance of certified products. A presumption of conformity with the essential requirements of the RED is obtained by the application of appropriate harmonised standards that are listed under the RED in the EU Official Journal. TUV SUD BABT will monitor changes to the Official Journal standards list, identify affected certificates and inform the certificate holders of changes which may affect the conformity of certified products. TUV SUD BABT will not inform certificate holders after the renewal date.

Annex A Information to be included within Technical Documentation

A.1 General

Each set of Technical Documentation is unique; as a result, there is no fixed structure. The following list identifies data and documents normally found to support the declaration of conformity.

It remains the responsibility of the manufacturer (or the person placing the product on the EU market) to hold the Technical Documentation and maintain its accuracy.

The Technical Documentation fundamental content requirements are explained in RED Article 21 and Annex V, but the directive itself also requires additional documentation (for example the risk assessment).

All documentation should be readily identifiable with either revision indication or an issue date. Multiple paged documents should have indications, page numbers or listed sections) to ensure they are complete.

The documentation to be included broadly falls into the following categories:

- Index
- Description of the radio equipment
- Procedures used to ensure conformity
- Test Data
- Other documentation

A.2 Index

The Technical Documentation should be structured in a logical format and have either a table of contents or an index.

Where the Technical Documentation covers multiple variants of a product the index/table of contents should be in sufficient detail to readily determine common items and documentation specific to single variants.

A.3 Description of the apparatus

The following documentation should be considered:

A.3.1 Overview

This should be an overview or brief description of the purpose of the apparatus and where more than one model of the apparatus is included in the Technical Documentation it should contain brief details of the relationships and differences between models.

A.3.2 Identification of Equipment

This should be a list of all model names and associated numbers of all product models included within the Technical Documentation. Where documentation is included using prototype names, or names from other markets then the relationship with the models named should be detailed. Supported radio interfaces and the associated parameters impacting compliance should be clearly identified (i.e. GSM 900, GPRS/EGPRS Class 33).

A.3.3 Block Diagram and/or Cross Connection Matrix

For more complex products a block diagram showing the following details should be supplied (for simple apparatus a complete circuit diagram may be satisfactory):

- points of connection to communications networks via any radio interfaces, showing antennas (internal or external)
- any other radio/wireless interfaces
- other ports (including ac power, dc power, signal & control)
- indicators of key functionality
- connections to earth (protective or functional).

Block Diagram and Cross Connection Matrix

The provision of a block/circuit diagram can help to ensure that all parties quickly reach a common understanding of the relevant tests and certifications required.

For complex equipment with switching capabilities, include a cross connection matrix showing the possible connections through the equipment between the various ports and/or terminating stations, if relevant to the assessment.

A.3.4 Technical Description explaining the Block Diagram

The block/circuit diagram should be accompanied by a brief technical description explaining how the equipment interacts with the communications networks concerned.

A.3.5 Circuit Diagrams and PCB Layout Diagrams

Detailed circuit diagrams and PCB layout diagrams are required for all circuits.

These should show all radio interface circuits, active speech processing devices, audio hybrids and transducers, power supplies and ports including any components providing user isolation. Circuit elements need only be shown in sufficient detail to explain the above. Circuit diagrams should exactly reflect the actual samples submitted for test.

A.3.6 Parts List (Bill of Materials)

You should include parts lists (BOMs) for those areas of circuit detail identified in the circuit diagrams.

Critical tolerances should be identified where applicable and the manufacturers of safety-critical components, all transducers and components affecting the signal path, including all second sources, should be stated. If more than one source of a critical component (e.g. line interface IC) is to be used, samples from all sources should be submitted for assessment.

A.3.7 Data Sheets

Where deemed necessary it may be useful to supply data sheets for any network/radio/safety critical components in the product although this is not a specific RED Annex V requirement.

A.3.8 Software and Firmware Versions

The version of any software or firmware supplied with the equipment which may affect compliance with the RED must be declared.

Where the relevant software or firmware is installed separately from the hardware (e.g. device drivers in PCs or plug in proms) then installation conditions must be provided either as a part of the software installation package or in the user guide.

Test Software: Where special software is provided to enable testing, then the version of such software must be recorded with a clear statement about the relationship of this software to the production sample. Note any test software being used still needs to consider compliance with RED Article 17 for the intended use of the product.

A.3.9 Photographs or Illustrations

Photographs or illustrations (assembly drawings / exploded diagrams) showing external features, marking and internal layout should be supplied. This should provide an adequate view so how the product is assembled and how sub-assemblies critical to the compliance of the product can be seen to fit together.

A.3.10 Statement of Intended and Foreseeable Use

As required by RED Article 17, the technical documentation must include a statement or explanation from the applicant of all intended operating conditions and, for the essential requirement of Article 3(1)(a) [Health & Safety], the statement / explanation must also take into account the reasonably foreseeable conditions. These statements can be part of the risk assessment (A.5.1 refers).

A.4 Procedures used to Ensure Compliance

A.4.1 Risk Analysis and Assessment

The compliance strategy should include an adequate analysis and assessment of the risk(s); and should take into account all intended operating conditions and, for the essential requirement of Article 3(1)(a) [Health & Safety], shall also take into account the reasonably foreseeable conditions as specified in the Statement of Intended and Foreseeable Use.

The risk assessment documents how the risks are addressed (mitigated) to ensure that the product complies with the essential requirements, including the identification of harmonised standards referenced in the Official Journal and other standards as required.

The risk assessment needs to include information for example for the use of non-harmonised standards and other additional guidance which then falls outside the scope of using Official Journal listed harmonised standards that provide a presumption of conformity.

A.4.2 Compliance Strategy

You should include documentation describing the compliance strategy including the measures for externally supplied sub-assemblies. Where the radio equipment can take different configurations, the compliance strategy and supporting technical documentation shall confirm that the radio equipment meets the essential requirements set out in Article 3 in all possible configurations.

The full details of compliance strategy can be part of the risk assessment.

Embedded Radio Module Technical Documentation

Where you rely upon Technical Documentation held by the supplier of a sub-assembly, e.g. self-contained Radio Modules, you should include any details necessary to meet the installation conditions of this assembly and arrange with the supplier to provide TUV SUD BABT with a copy of their Technical Documentation. We understand that the Technical Documentation is confidential and may be made available only to TUV SUD BABT, and not the applicant for certification.

A.4.3 List of Standards Applied

You should include a list of all relevant standards applied to ensure conformity. This list should include the issue level of the standard.

Where you have only partly applied relevant standards, the technical documentation should specify the parts which have been applied.

A.4.4 Justifications

Where relevant you should include the following justifications:

- **Justification of tests not performed**
  If there are any aspects for which testing has not been performed then a clear technical justification for this shall be provided. This should include details of what alternative processes have taken place to establish compliance to the essential requirements.
- **Justification for using test data from a different standard**
  Where you use test data from other standards this may be included instead of the harmonised standard with a justification for using this to demonstrate compliance to the relevant essential requirement. For example, you may have test data from testing to a non-harmonised standard derived from the same global standard.
- **Justification for omitting tests**
  Where the functionality of your equipment does not encompass a normal sub-set of tests from a standard you should provide a justification for omitting those tests;
  Where due to design constraints, or industry wide lack of test capability tests cannot be performed then you should include justifications (with appropriate supporting data) why the apparatus complies with the requirement

A.5 Test Data

A.5.1 Test Reports

These should broadly follow the guidelines in ISO/IEC 17025 Clause 5.10.

Although ISO 17025 accredited reports are always preferable, use of non-accredited Test Facilities is acceptable, please refer to BABT 766 Sources of Test Reports for TUV SUD BABT Product Certification, Section 12. As explained in BABT 766 Section 12 acceptance of these reports is dependent on for example if the lab has any current accreditations for similar specifications or quality managements systems. Additionally, it may be necessary to supply further supporting documentation and possibly witnessed testing may be required to support non-accredited test reports.

A.5.2 Design Calculations

Where you use design calculations instead of independent test data, or to supplement it, these should be clearly included.

A.5.3 Test Methods

Where the standards used do not include test methods or where alternate test methods have been used they should be detailed with justifications for their appropriateness to demonstrate the requirement.

Details should include the equipment used, the calibration status of test equipment, and the estimated measurement uncertainty.

A.5.4 Justifications

The following justifications should be included as appropriate:

- **Related Products/Models**

  Where the Technical Documentation covers a range of related products or models the test reports shall be sufficient to cover the range taking into consideration the supporting documentation of similarity between products. Where differences in implementation could affect particular requirements, testing to those requirements should take place on sufficient variants to cover each different implementation. The justifications to limit testing should either be included with the data or product descriptions

- **Validity of test results obtained prior to modification**

  Where you include test results obtained using apparatus at a build level different from the current level then there should be a justification of the continuing validity of those results. This may be in the form of a positive assertion of the results, or a negative assertion of any effect on the compliance held against individual engineering changes

A.6 Other Results

Results of design calculations made, examinations carried out, and other relevant similar elements.

A.7 Other documentation

A.7.1 An Explanation of Compliance with Article 10(2) and 10(10).

As required by RED Annex V (i) the technical documentation needs to include an explanation of compliance to

- Article 10(2), that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.
- Article 10(10), where there are restrictions on putting into service or of requirements for authorisation of use Article 10(10) has been complied with. The technical documentation should include an explanation of compliance to Article 10(10) even if considered not applicable to the product as required by RED Annex V(i).

If applicable Article 10(10) has specific requirements for packaging and the user instructions which will be assessed as part of the Annex III type examination. Please refer to Commission Implementing Regulation (EU) 2017/1354 20 July 2017 for guidance on this requirement both for the user instructions and the required pictogram on the packaging artwork.

A.7.2 Authorised Representative Mandate

If the manufacturer has appointed an Authorised Representative in accordance with RED Article 11, the written mandate for this appointment should be included in the technical documentation.

A.7.3 User/Installation/Special Instructions

You should supply (in English) a draft or published set of User Instructions, or for complex equipment, those sections of the user instructions which relate to compliance with the RED. They should:

- for radio transmitting equipment, include
  - the frequency band(s) in which the radio equipment operates; and
  - the maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.
- include either a copy of the full Declaration of Conformity in accordance with RED Annex VI, or a simplified Declaration of Conformity in accordance with RED Annex VII with details of the internet address where to obtain the full Declaration of Conformity;
- include all required regulatory information e.g. restrictions on putting into service or requirements for authorisation of use i.e. with respect to RED Article 10(10);
- include information where licensing is required;
- include all the information required for conformance to the relevant standard;
- include all safety information for the product;
- include instructions on the intended use of the product including where applicable a description of accessories and components required for it operation;

A.7.4 CE Marking and Other Product Labelling

The Technical documentation should include an adequate example / explanation of the details for the product CE marking in accordance with Regulation (EC) No 765/2008 and other product labelling requirements in accordance with RED Article 10(6) and 10(7).

A.7.5 Declaration of Conformity (DoC)

The Technical Documentation should contain a Declaration of Conformity to the RED in accordance with RED Annex VI. This may be in draft form at the time of submittal to TUV SUD BABT but must be formally issued prior to application of the CE mark on products.

The RED requires a single DoC identifying all applicable Union acts/directives. However, to reduce the administrative burden, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity. Please see Recital 42 and Article 18 of the RED.

Annex B Standard Product Types

TUV SUD BABT use standard product types for certain types of our certificates

Where possible please categorise your equipment on the BABT 500 application form under one of the following types. Where your product does not readily match any of the listed types of product please provide a brief description so that we can generate an appropriate Certificate entry. Where the product could be classified under multiple product types, the primary type should be listed (i.e. an LTE/WCDMA/GSM mobile phone with WLAN and Bluetooth should just be listed as a LTE/WCDMA/GSM Device.

Product Type	**Additional Comment**
LTE/WCDMA/GSM Device or Cellular Phone	-
Short Range Device	As described by ECC Recommendation 70-03
Base station	All base station equipment for all technologies
GSM Device of Cellular Phone	-
WCDMA Device of Cellular Phone	-
WCDMA/GSM Device of Cellular Phone	-
LTE Device of Cellular Phone	-
LTE/WCDMA Device of Cellular Phone	-
LTE/GSM Device of Cellular Phone	-
WLAN Device	-
Broadcast Radio receiver	-
Industrial, Scientific and Medical equipment	-
Other	Provide an additional explanation of the technology not falling under the broad product categories above.

Annex C Example EU Declaration of Conformity Content

We,

(Manufacturer's name)

Of

(Address)

Declare under our sole responsibility that the product:

(Detailed description of product including batch or serial number, name, type, model, and, where necessary, a colour image; where applicable a description of accessories and components, and software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity)

to which this declaration relates, is in conformity with the following standards and/or technical specifications *(References to standards/specifications must be listed with their identification number and version and, where applicable, date of issue)*

Health & Safety (Article 3.1(a)): ---

EMC (Article 3.1(b)): ---

Radio Spectrum (Article 3.2): ---

Other (Article 3.3) *(if applicable)*: ---

We hereby declare that the above-named product is in conformity to all the essential requirements of Directive 2014/53/EU with the involvement of the following Notified Body under Annex III Module B of the Directive *(Where the TUV SUD BABT Type Examination Certificate / involvement is only for limited articles, i.e. Article 3.2 only this should be explicitly stated here):*

TUV SUD BABT, Octagon House, Concorde Way, Fareham, Hampshire, PO15 5RL, United Kingdom

Identification mark: **0168** *(Notified Body number)*

Type Examination Certificate No: **Enter Certificate Number Here**

The technical documentation relevant to the above equipment will be held at:

(Name and address of EU representative)

(Signature of authorised person)

(Date)

(Name of authorised person)

(Place of issue; e.g. City/town, and Country)

(Job title)

Note (not forming part of this declaration): The information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity. Please see Recital 42 and Article 18 of the RED.