BABT 746

TUV SUD BABT Implementation of Annex III Module B, of EMC Directive 2014/30/EU - EU-Type Examination

A Certification Body of

Foreword

This guide explains the TUV SUD BABT Implementation of Annex III Module B of the Electromagnetic Compatibility Directive, 2014/30/EU – EU Type Examination.

The scheme enables a manufacturer of product within the scope of the EMC 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 TÜV SÜD Certification Regulations.

All TUV SUD BABT publications are available from:

http://www.tuv-sud.co.uk/babt

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1. Introduction

1.1 Scope

This document explains the TUV SUD BABT (the Certification Body) Implementation of Annex III Module B of the Electromagnetic Compatibility Directive, 2014/30/EU.

1.2 Overview

The formal output from the Certification Body is a Type Examination Certificate.

Where the Technical Documentation does not demonstrate the required compliance, the formal output is in the form of an e-mail or letter informing the applicant, TUV SUD BABT's notifying authority and all other EMC Directive Conformity Assessment Bodies, of the results of the assessment (see 2.7.3).

2. Making an Application

2.1 Who to Apply To

The application should normally be made to your local TÜV SÜD office. If you do not know your local office, you may apply to TUV SUD Product Service Ltd at the same address as TUV SUD BABT (refer to the foreword).

The Application must be made using form BABT 300 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 of equipment within the scope of Directive 2014/30/EU. The person making the application should be a duly authorised signatory of the applicant and may not be an agent or an employee of the Certification Body.

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

The Certification Body 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

2.3 Types of Application

The application should be made for Annex III Module B Type Examination on form BABT 300.

You should indicate the essential requirements which you wish the Certification Body to review. The Certification Body recommends that both Emissions and Immunity are reviewed.

You should further indicate whether this is an original submission, modification or a variant to technical documentation for which the Certification Body has already issued a Type Examination Certificate.

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

OEM, Brandname, or badge engineered products which are identical apart from product naming and cosmetic "Branding" items may be included with the original application. Alternatively, separate applications may be made

Derived Products or "Sisters": 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.

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 300.

Section A: Contact Details

- **Section A.1: Details of the Main Contact within the Applicant Company**
  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 a consultant or agent, unless the application is accompanied by evidence that the agent is authorised to act on the applicant's behalf.
- **Section A.2: Other Contact 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. You may not request the name of a company outside your corporate structure.

  Consultant/Agent details where you have used a consultant/agent to assist or submit the application.

Section B: Your Certification Requirements

As described above.

Section C: Product Details

- **Section C.1: Product(s) Submitted**
  This must be clearly stated as this will appear on the certificate and serve as a prime identifier of the certified product(s).

  The 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.
- **Section C.2: Brief Description of the Product including its intended purpose**

  This should be in sufficient detail to enable the Certification Body to understand the product and ensure it is within the Scope of the appointment and legally able to be sold.
- **Section C.3: Product Type**

  Please list the product type and any additional description. Note to assist you the form includes a drop-down menu of the most popular product types.
- **Section C.4: Related Products**

  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.

  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.

Section E: Agreement

- A declaration that the specified product is not the subject of an application under the same Directive to another Notified Body acting in a similar capacity to TUV SUD BABT
- A statement that you understand and agree to abide by the TÜV SÜD Certification Regulations.
- The application should also be accompanied with supporting information as detailed in later sections.

2.5 Technical Documentation

2.5.1 General

The completed BABT 300 application form should be accompanied by technical documentation.

The technical documentation must be sent via electronic media (e.g. On a CD, or via e-mail attachments). 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 the Certification Body 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, the submitted technical documentation should contain the following information.

- Index or Content list
- Description of the apparatus
- Procedures to ensure compliance
- Test Data
- User Instructions

  An explanation of the compliance with the requirement of Article 7(2) and relevant packaging details

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

2.6 Progressing the Application

When the Certification Body has received your application and evaluated the initial information, we will:

- inform you of the 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 the Certification Body has received all the required items the application will be allocated to an engineer for formal review.

2.7 Completion of Annex III Module B Process

2.7.1 Assessment Process

The Certification Body 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 EMC directive.

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 are inconsistent or omitted;

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 suspended at an appropriate time and will only be resumed after the 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
- suspend the assessment and obtain the additional required tests results.

Where the testing option is taken, then this must take place at either a test facility recognised by the Certification Body or at any other Test facility accredited to ISO/IEC 17025 (or equivalent). In the latter case TUV SUD BABT may require evidence of accreditation for the tests being performed.

Once the required testing has been performed the test report should be sent to the Certification Body so that the assessment can be 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, the Certification Body 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 the Certification Body
- The EMC 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
- Other data necessary for identification of the product, and any conditions for its validity.

The Certificate only relates to the inspected Technical Documentation

- If the Technical Documentation in the opinion of the Certification Body does not demonstrate compliance with the requirements of the Directive, a letter informing the applicant of the results of the assessment will be issued.

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 the Certification Body then:

- Where the certificate covers all the relevant requirements of article 6 of the EMC directive you may draw up a Declaration of Conformity to the EMC directive. (a pro-forma Declaration may be found in Annex C of this guide);
- 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.

Where the Certification Body are issuing an unfavourable certification decision or apply specific unrequested conditions within a certificate on the installation or use of the apparatus, the Certification Body will inform the client in writing.

In these circumstances the client has up to 28 days to make representation to why a favourable certification decision should be made, or why the proposed condition should be lifted.

Appeal Timescale

Where you do not wish to make representation to overturn the certification decision it is helpful if this is indicated as soon as possible such that the process can be formally concluded without delay.

Where the Certification Body issues an unfavourable certification decision this shall be communicated to you in writing, with a copy being sent to the UK Government Department for Business, Energy and Industrial Strategy (BEIS) for information.

It is then your choice whether to

- rectify the concerns and apply for another Type Examination Certificate; or
- rectify the concerns and follow another option as appropriate to your equipment (e.g. follow the standards route); or
- desist from marketing the product in the EU

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

the Certification Body 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, the Certification Body 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.

the Certification Body is required to inform the UK Government UK Government Department for Business, Energy and Industrial Strategy (BEIS), our notifying authority, of Type Examination Certificates and their modifications which we have issued or withdrawn and make available to DBIS the list of certificates and their modifications that have been refused, suspended or otherwise restricted.

the Certification Body is required to inform the other EMC Directive notified bodies about Type Examination Certificates and their modifications which we have refused, withdrawn, suspended or otherwise restricted, and, upon request, about certificates and their modifications which we have issued.

The Member States, the European Commission and the other EMC Directive 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 in the Directive for 10 years after the apparatus has been placed on the market.

3. Regulatory Marking

The CE marking in respect of the Directive shall be applied only to equipment for which a valid Declaration of Conformity exists.

The apparatus must be marked with a type, batch or serial number or other element allowing its identification, or, where the size or nature of the apparatus does not allow it, the required information is provided on the packaging, or in a document accompanying the apparatus.

The apparatus must be marked with the manufacturer's (or authorised representative's or importer's) registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging, or in a document accompanying the apparatus. The address shall indicate a single point at which the manufacturer can be contacted.

The apparatus must be accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

It is not permitted to associate any Notified Bodies identification after the CE mark to indicate the involvement of a Notified Body.

CE Mark

You may obtain an electronic copy of the CE Mark from either Customer Services or from the TUV SUD BABT Web site. (See the Foreword of this guide for details).

4. References to TUV SUD BABT Notified Body

While it is not permitted to attach the Notified Body Number (0168) to the CE mark it is permitted to reference the Certification Body (including the number) in the Declaration of Conformity (referencing the Annex III conformity procedure).

No non-regulatory Product Mark is available for EMC under this Scheme.

5. Intended Purpose

You are required to provide information with the product to enable use in accordance with the intended purpose of the apparatus. This must be in a form suitable to accompany the product.

6. Keeping your TCF up to Date

6.1 General

During the lifetime of a certified product, the Certification Body 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 EMC Directive 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 EMC directive 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 EMC directive or the conditions for validity of the certificate require approval by TUV SUD BABT.

6.2 Administrative Changes

Where the Certification Body has issued a Type Examination Certificate and details on the certificate unrelated to compliance with the EMC Directive require change (e.g. Company address, Product name) then you may apply for an updated Certificate based upon the original assessment.

6.3 Product Changes

Where a change to a certified product has occurred that may affect its conformity with the essential requirements of the EMC Directive or the conditions for validity of the certificate, you should apply to the Certification Body 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.

The application may be made in writing or by electronic means.

Alternatively, you may either apply to the Certification Body for a completely new assessment or progress the change through an appropriate EMC Directive 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.

6.4 Changes to the State of the Art

A presumption of conformity with the essential requirements of the EMC Directive is obtained by the application of appropriate harmonised standards that are listed under the EMC Directive in the EU Official Journal. the Certification Body will monitor changes to the Official Journal standards list and inform certificate holders of changes which may affect the conformity of certified products.

Annex A - Information to be Included Within the 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.

For applications to the Certification Body we prefer that the technical documentation is sent via electronic media (e.g. on a CD, or via e-mail attachments). Documents should be in Word, Excel, Adobe PDF or JPEG formats. Where you wish to use other electronic formats or employ encoding please contact the Certification Body prior to submission to ensure the Certification Body's access to the files. Zipped files should be in WinZip format. Where you submit the technical documentation in paper form the Certification Body may charge a handling fee.

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 Apparatus
- Procedures used to ensure conformity
- Test Data
- A copy of the EU Declaration of Conformity
- 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.

A.3.3 Block Diagram and/or Cross Connection Matrix

- You may include a block diagram showing the following details (for simple apparatus a complete circuit diagram may be satisfactory):
- points of connection to communications networks via any wire or optical interfaces
- 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 which may influence conformity.

These should show all network interface circuits, active speech processing devices, audio hybrids and transducers, line signalling components, power supplies, ports and all network-affecting circuit elements 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

Data sheets for any safety critical components including Gas discharge tubes and other voltage dependant devices.

A.3.8 Software and Firmware Versions

The version of any software or firmware supplied with the equipment which may affect compliance with the EMC Directive 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.

A.3.9 Photographs or Illustrations

Photographs or illustrations showing external features, marking and internal layout.

A.4 Procedures used to ensure compliance

A.4.1 Compliance Strategy

You should include documentation describing the compliance strategy including the measures for externally supplied sub-assemblies.

A.4.2 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.4.3 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.4.4 Risk analysis

The technical documentation shall include an adequate analysis and assessment of the risk(s) to conformity with the applicable requirements of the Directive.

A.5 Test Data

A.5.1 Test Reports

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

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 TCF 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 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

A.6.1 Other Results

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

A.7 Other Documentation

A.7.1 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 EMC directive. They should:

- contain all the information required for conformance to the relevant standard;
- include either a copy of the Declaration of Conformity, or a short form declaration to the EMC directive with details of the internet address where to obtain the full Declaration of Conformity;
- not give details of adjustments which can take the equipment outside compliance - unless it is made clear how to adjust the equipment to maintain compliance and that any non-compliant setting would invalidate the certification.

A.7.2 Declaration of Conformity

The technical documentation should contain a Declaration of Conformity to the EMC Directive. This may be in draft form at the time of submittal to the Certification Body but must be formally issued prior to application of the CE mark on products.

The EMC Directive requires a single Declaration of Conformity 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 34 and Article 15 of the EMC Directive.

A.7.3 Operation in at Least One Member State

An explanation of the compliance with the requirement of Article 7(2) of the EMC Directive and of the inclusion or not of information on the packaging in accordance with Article 7(8).

Annex B - Example EMC EU Declaration of Conformity Content

We, ----------
(Manufacturer's name)
Of

(Address)
Declare under our sole responsibility that the product:

(Detailed description of product including name, type, model and supplementary information such as lot, batch or serial number, sources and number of items)
to which this declaration relates, is in conformity with the following standards and/or other normative documents.

We hereby declare that the above-named product is in conformity to the essential requirements of Directive 2014/30/EU with the involvement of the following Notified Body(is) under Annex III Module B of the Directive:

TUV SUD BABT UNLIMITED, 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)*

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(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. 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 34 and Article 15 of the EMC Directive.