***TOPAS Registration Technical File***

***For***

***<Generic Product name>***

*<Enter the name of the product>*

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| **Revision** | **Date** | **Scope** | **Authorised by** |
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*<Enter the issue (revision) status of this document>*

*<****Important Note:*** *any changes to the content of the document should always result in an up-issue of the revision status, so that it is always clear which is the latest version.>*

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*<Enter any appropriate Copyright information>*

***Guidance on using this document***

*This document provides a template which may be used to create a Technical File suitable for application for TOPAS Product Registration. Other document formats are permitted but all Technical Files should follow the general principals contained herein.*

*It is particularly important that Technical Files maintain accurate revision (issue) state control. Where changes to the document itself, or any referenced material are made, these must be properly signified by the up-issue of the Technical file and any changed material which might be referenced by it.*

*Once complete these guidance notes and any other instructions throughout the document, signified by the angled brackets, < instruction>, should be deleted.*

**CHANGE HISTORY**

<This section is mandatory and must be used to record changes to the Technical File and is particularly helpful to the Technical Assessor if multiple iterations of the document are required to reach a state where the product is recommended for Registration.>

<Remember to keep the Issue state contained in the footer up to date>

|  |  |
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| **Revision** | **Summary of changes** |
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# TABLE of CONTENTS

<This section is mandatory and must list everything that is contained within the Technical File.>

<If there are iterations of the Technical File or any reference documents are amended, they must be up-issued and the new revision (issue) information noted in this TOC.>

|  |  |
| --- | --- |
| **Content** | **Reference or Page** |
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| Function design description (SDD) | 3 |
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<If the material is contained within the Technical File simply insert the page number as a reference. (The template pages are currently auto-numbered so if the pages contained in this template are used the page number references should change automatically as new material is added or deleted).>

<If the material is supplied separately the full document name (file name) and revision (issue) state must be included either here or within the referenced pages **– remember to update this TOC and the revision state of the overall Technical File should any referenced material change**!>

<The exact content required for the technical File is defined in each TOPAS specification, so not all sections will necessarily be required – entries for any sections which are not required may be deleted or simply marked as N/A.>

# OVERVIEW AND PRODUCT DESCRIPTION

<Provide a brief overview of the Product or Product family to be Registered>

<This need not be highly detailed but if several product variants within a Product family are being Registered, sufficient information should be provided to enable a Technical Assessor to understand the scope of the family, particularly if different test results or other material (such as the Statement of Compliance) are to be provided for different family members. Pictures and diagrams may be included as necessary.>

# Functional Design Description

<Provide a reference to the overall System Design Document (SDD) by name, document number and revision (issue) state.>

<It is not required that the actual System Design Document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than one System Design Document list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 010-2317-00 | 4 | System Design Document for Labfine LV Controller |
| 010-2317-01 | 3 | System Design Document for Labfine ELV Controller |
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# Product part numbers

<Provide a list of the top-level part number(s) and revision (issue) states of the Product or Product family to be Registered. The list is not required to cover every individual item or assembly that makes up a Product, but only significant items which are likely to be recognised and purchased>.

<For many simple products, such as detectors, this may just be a list of the top-level items which make up a Product family. For more complex products such as traffic controllers, the list may also include important sub-assemblies which are used to customise the controller for delivery>.

<It is recognised that changes to important product sub-elements do not always change the issue state of parent items and may therefore go unnoticed. Where this is the case, the Manufacturer should also consider identifying key sub-elements, whose issue state can be tracked, to identify where significant product change has taken place.

<Where it is the case that key operating software or firmware may be updated without the issue state of parent parts being affected, the issue state of the software / firmware must always be explicitly listed).

<**Important Note** - The list should be the same as that provided as part of the Declaration of Conformity (TOPAS form T001), as the alignment of the two documents helps the Technical Assessor ensure that all items to be Registered are properly covered by the Technical File>.

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Part Number** | **Issue state** | **Description** |
| 657-2317-00 | 3 | Labfine LV Controller 2-8 phase |
| 657-2317-01 | 4 | Labfine LV Controller 9-16 phase |
| 657-2317-02 | 3 | Labfine LV Controller 17-24 phase |
| 657-2317-03 | 2 | Labfine LV Controller 25-32 phase |
|  |  |  |
| 626-0012-10 | 2 | 1 KVA Dimming transformer assembly |
| 626-0012-20 | 1 | 2 KVA Dimming transformer assembly |
|  |  |  |
| 630-01245-04 | 5 | I/O Board assembly 16 inputs – 4 outputs |
| 630-01245-16 | 2 | I/O Board assembly 16 inputs – 16 outputs |
|  |  |  |
| 623-1601-05 | 5 | Labfine LV Controller main operating firmware |
| 623-1602-03 | 3 | Labfine LV Controller safety system firmware |
| 623-1603-03 | 3 | Labfine LV Controller I/O system firmware |
| 623-1604-06 | 6 | Labfine LV Controller Int OTU/OMU firmware |
|  |  |  |

# QA Certification certificates

<Provide a copy of the Quality Management Registration Certificates for the **Manufacturer** of the Product for which TOPAS Registration and being applied for>

<This may be pasted into this page or supplied separately and properly reference here or in the Table of Contents>

# CE / CA marking documentation

<Provide a list of a list of all directives complied with and how such compliance is achieved. Typically, this would be references to explicit CE / CA Technical Files. Copies of the CE / CA certificate’s must be included as part of this Technical File.>

<The certificates may be pasted directly into this document or supplied separately and properly reference here.>

# Statement of compliaNCE

<Provide a clause-by-clause statement of compliance against the TOPAS specification for which Registration is being sought, confirming compliance and/or listing caveats or deviations.>

<**Important Note:** Applicants are advised, where possible, to use the SOC compliance matrix template defined in TOPAS form T006 and take note of the comprehensive guidance contained within that template.>

<However, the use of the template is not mandatory and alternative manufacturer specific templates and documents may be provided in support of a TOPAS Registration Application, but they must at least:

* Be formal documents which have their own part number and revision (issue) state.
* Individually address each clause in the TOPAS specification, clearly indicate compliance and identify where compliance is proved, by reference to appropriate test schedules and results. **Note that it is not permitted to simply miss out clauses of the specification!**
* Clearly identify where a product is non-compliant with a clause, and the nature of the non-compliance clearly noted.>

<Typically, it is expected that a single SOC will apply to a whole product family, but where this is not the case separate SOC’s may be provided for different family members, or alternatively a single SOC may identify a set of common clauses and separately list variations for different family members.>

<It is generally expected that the SOC(s) will be supplied separately and referenced either here or directly in the Table of Contents. However, as an alternative for very small specifications, the SOC may be included directly in this Technical File.>

# test procedures and results

<Provide a list of the functional test procedure and test result documents which have been used to verify the performance of the product and in particular its compliance with the relevant TOPAS specification.>

These documents listed should be at least those which are referred in the SOC as evidence that sufficient testing has been undertaken to confirm compliance with each clause of the TOPAS specification.

<**Important Note** – It is not required that the actual test documents are provided here, only that they are listed by name, revision (issue) state and description. Also results for EMC, Environmental, Radio Regulations testing and any Primary Safety Testing (for Controllers), need not be listed here as evidence for these must be separately provided elsewhere in the Technical File.>

<A short example list is provided below, based around the example Statement of Compliance contained in TOPAS form T006.>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| TP-23576-10 | 3 | System Test Results (SOC Ref 1) |
| TP-23576-01 | 6 | Software Module Test Results (SOC Ref 2) |
| TP-23576-02 | 2 | Software Module Test Results (SOC Ref 3) |
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# EMC Test Results

< If EMC testing is required by the TOPAS product specification, TOPAS 2130 or TOPAS 0600, it is expected that an EMC test requirement document is produced, outlining to the Test House what tests are required and defining any special set up required for the tests.>

<It is not required that the actual test requirement document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than one test requirement document, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<Copies of the actual EMC test results **must** be included as part of the Technical File. These may be pasted directly into this document or supplied separately and properly reference here>.

<If for a family of products, there is more than one set of EMC test results, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 700-2317-00 | 3 | EMC Test Requirements for Labfine LV Controller |
| 700-2317-01 | 1 | EMC Test Requirements for Labfine ELV Controller |
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| 701-2317-00 | 2 | EMC Test Results for Labfine LV Controller |
| 701-2317-01 | 2 | EMC Test Results for Labfine ELV Controller |
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# optical Test Results

<If optical testing is required by the TOPAS product specification, TOPAS 2130 or TOPAS 0600, it is expected that an optical test requirement document is produced, outlining to the Test House what tests are required and defining any special set up required for the tests.>

<It is not required that the actual test requirement document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than one test requirement document, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<Copies of the actual Optical test results **must** be included as part of the Technical File. These may be pasted directly into this document or supplied separately and properly reference here>.

<If for a family of products there is more than one set of Optical test results, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 010-0012-00 | 1 | Optical Test Requirements for Labfine 200mm LED signal |
| 010-0012-01 | 1 | Optical Test Requirements for Labfine 100mm LED signal |
|  |  |  |
| 120-0012-00 | 3 | Optical Test Results for Labfine 200mm LED signal |
| 120-0012-01 | 1 | Optical Test Results for Labfine 100mm LED signal |
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# environmental Test Results

<If environmental testing is required by the TOPAS product specification, TOPAS 2130 or TOPAS 0600, it is expected that an environmental test requirement document is produced, outlining to the Test House what tests are required and defining any special set up required for the tests.>

<It is not required that the actual test requirement document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than one test requirement document, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<Copies of the actual environment test results or a test certificate **must** be included as part of the Technical File. These may be pasted directly into this document or supplied separately and properly referenced here>.

<**Important Note** – For environmental test it is permitted to supply a test certificate in place of the full test results. See TOPAS 0600 for more details on the restrictions around the provision of environmental test certificates in lieu of full test results).>

<If for a family of products there is more than one set of Environmental test results, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 710-2317-00 | 2 | Environmental Test Requirements for Labfine LV Controller |
| 710-2317-01 | 2 | Environmental Test Requirements for Labfine ELV Controller |
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| 711-2317-00 | 1 | Environmental Test Results for Labfine LV Controller |
| 711-2317-01 | 2 | Environmental Test Results for Labfine ELV Controller |
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# radio test results

<If radio testing is required by the TOPAS product specification, TOPAS 2130 or TOPAS 0600, copies of the reports or results of radio testing undertaken by an appropriately qualified independent approved test house, must be included in the Technical File Pack.

The reports or results should be those listed on the Radio Equipment Regulations Declaration of Conformity and its associated Technical File and cover any specific IR 2030 requirements for the type or radio equipment employed.

<**Important Note:** Where an individual TOPAS Technical Product Specification does not contain explicit radio requirements, but the Product does include a radio transmitter, receiver or transceiver, compliance with the Radio Equipment Regulations (2017) is required and the compliance documentation outlined above must be included in the Technical File.

<Copies of the test results / reports **must** be included as part of the Technical File. These may be pasted directly into this document or supplied separately and properly referenced here>.

<If for a family of products there is more than one set of radio testing results, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 731-2317-00 | 1 | Radio testing report for Labfine Controller family |
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# primary SAFETY test results

<Primary testing is usually only required for traffic control equipment. If required by the TOPAS product specification, it is expected that a primary test requirement (schedule) document is produced, outlining what tests are required and defining any special set up required for the tests.>

<It is not required that the actual test requirement document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than one test requirement document, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

<Copies of the actual primary test results **must** be included as part of the Technical File. These may be pasted directly into this document or supplied separately and properly referenced here>.

<If for a family of products there is more than one set of primary test results, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

**<Note about primary tests**: Primary Tests are a set of special test which are undertaken to verify that the basic safety facilities of a traffic signal controller function correctly.>

<As a very minimum the tests should therefore verify compliance with the primary safety requirements defined in TSRGD, for ‘signal states endangering traffic”, so Green-green conflict (AA1), Green-yellow conflict (AB1), Green-red/yellow conflicts (AD1) and compliance (AD1), all from EN12675.>

<In addition, other tests may be required to ensure that controller functions in a safely and would usually include tests to verify:

* Correct start-up after power failure, including the correct implementation of the start-up sequence.
* Correct implementation of the basic signal sequences.
* Correct response to watchdog failures.
* Correct response to failures of program or configuration checksums.
* Correct functioning of the Red Lamp monitoring system
* All signal sequences are implemented correctly
* Proper protection of safety timings against incorrect modification>

<Typically, it is expected that these are undertaken whenever there is a change to the controller firmware (or less often for any hardware which could impact on the safety functionality of the controller).>

<A short example list is provided below:>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 730-2317-00 | 4 | Primary Test Requirements for Labfine LV Controller |
| 730-2317-01 | 1 | Primary Test Requirements for Labfine ELV Controller |
|  |  |  |
| 731-2317-00 | 2 | Primary Test Results for Labfine LV Controller |
| 731-2317-01 | 2 | Primary Test Results for Labfine ELV Controller |
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# failure mode analysis

<Failure mode analysis testing is usually only required for traffic control equipment. If required by the TOPAS Product Specification a failure mode analysis must be performed as outlined in EN 50556.>

<It is not required that the actual detail of the failure mode analysis test requirement document is provided as part of the Technical File, only that it is identified and listed by name, revision (issue) state and description. If for a family of products there is more than failure mode analysis, list each of them here, ensuring that it is clear to which member of the product family each one refers.>

|  |  |  |
| --- | --- | --- |
| **Document Number** | **Issue state** | **Description** |
| 740-2317-00 | 7 | Failure mode analysis document for Labfine LV Controller |
| 740-2317-01 | 5 | Failure mode analysis document for Labfine LV Controller for Labfine ELV Controller |
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End of Technical File