Project no.: Order no.:

Test and certification system (PZO)

Eurofins Product Service GmbH

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1. Scope

The test and certification system (PZO) regulates the execution of the services stated below by Eurofins Product Service GmbH (Eurofins):

- Tests and appraisals of technical products, components and technical product blueprints e.g. with regard to safety, serviceability, quality and environmental-friendliness based on statutory regulations, national, European and international standards as well as requirements agreed with the customers
- Evaluations and assessments of test and audit reports,
- Certifications of products and recognitions of QM systems
- Appraisals and inspections of factories with regard to quality-assuring measures when issuing quality marks or proof of conformity
- Monitoring of certified or approved QM systems
- Tests and assessments of technical documentation.

The EUROFINS operates worldwide and offers the service to all customers without restriction. Countries or areas are excepted therefrom, which are suspended or prohibited by accreditation or recognition authorities.

2. Test system

2.1 Basic requirements

The customer (manufacturer or distributor/importer of a product), hereinafter referred to as "Customer", commissions Eurofins Product Service GmbH, hereinafter referred to as "EUROFINS", with a product test, certification or with the examination of a QM system.
The order can be placed without a form in writing or verbally. An order placed verbally will be re-confirmed in writing.
When placing a test order and/or commissioning a certification (certification agreement) from EUROFINS, it shall conclude a general contract with the Customer using the order form and/or the Application Form. The order may be granted in writing or orally. Generally, a written confirmation with an order confirmation is made. If another Eurofins branch attends to the customer, an additional authorization (POA = Power of Attorney) is required. The basic conditions for the future cooperation shall be regulated with this contract in conjunction with the General Business Terms and the PZO. The Customer must be registered under commercial law with its company.
If the Customer endeavours to achieve a certification of its product then it must document, under which model designation or trade name its company would like to sell and distribute the product which is to be certified.
A conducted test with a final expert's opinion or a certificate does not indemnify the Customer from its statutory product liability. In case of non-determined defects EUROFINS shall only then have co-liability, if there was gross negligence with the test process. EUROFINS has a Commercial General Liability Coverage and Environmental Coverage with a combined single limit of 5.000.000€ for bodily injury, property damage and pure financial loss. Also insured, within the scope and conditions of the contract, is the personal legal liability of the Eurofins test laboratories for their activities for the certification body.

2.2 Place of tests

Tests are as a rule carried out in laboratories of EUROFINS or in laboratories which are affiliated with EUROFINS as per contract.
Depending on the product, other test locations can also be agreed if it is ensured that the test environment does not influence the test results and meets the test requirements. The decision about the test location is the responsibility of EUROFINS. If the test is to be carried out for the purpose of a subsequent certification then the test location must be recognised by the certification body.
By coordination with the customer the tests can also be carried out in third party laboratories or in the laboratories of the Customer if these are recognised for the corresponding tests e.g. by the Deutsche Akkreditierungsstelle (DAkkS) or another ILAC member, have been assessed positively or the requirements of DIN EN ISO/IEC 17025 have been proven for tests through an appraisal by the certification body of EUROFINS.
A given promise to carry out external tests can be revoked by EUROFINS if the satisfaction of the requirements of DIN EN ISO/IEC 17025 is no longer ensured or if complaints of the certification body of EUROFINS are not filed with reference to the test laboratory.
If employees of the Customer participate in conducting the test then the work may only be carried out in the presence and under the supervision of an expert of EUROFINS (Witness Testing). In this case the Customer undertakes to indemnify EUROFINS from obligations for damages for the event that an employee of the Customer wilfully or negligently breaches a duty during the test. The indemnification obligation also comprises in-court and out-of-court costs.

2.3 Test procedure

After the placing of the order the Customer shall forward at least one test sample to EUROFINS free of charge together with the full technical documents which are necessary for the assessment (e.g. set-up overview, operating instructions, certificates of used safety-technical components, other technical documentation). If required EUROFINS can subsequently request several test samples free of charge. The test sample is tested based on the statutory regulations, rules and the current state of the art. If no standards or statutory regulations exist for the type and scope of the test or if the customer explicitly insists on test bases which deviate from this then EUROFINS shall stipulate a test program. The test orders shall be processed under the pre-requisite of the full submission of all necessary documents and test samples. Test and certification documentation should generally be submitted in German or English. This applies both to product as well as to QM system tests.
If the customer endeavours to achieve a test mark approval (e.g. GS-Mark, Eurofins- BG-Mark) with the product test and if the course of the test allows a positive result to be expected EUROFINS shall carry out an initial factories inspection by coordination with the Customer, in which the production, assembly and test equipment as well as the QM measures are examined, which are necessary for the continuous compliance with a quality which is equivalent to the assessed building sample. After completion of the test process the Customer shall receive a written notification or a short report or in the event of an appraisal an expert's opinion.
In case of faulty tests the report (report of defects) shall present the determined deviations. Except in the event of an expert's opinion the Customer shall only be made available against a separate calculation of the full test report at special request.
If the test process did not show any complaints and if a certification was commissioned then the test report shall be forwarded to the certification body for certification with the relevant technical documents.

2.4 Location of test samples and documentation

In case not otherwise agreed in the order as a standard after completion of the tests, as well as after the test process is aborted, the test samples will be returned to the Customer at its costs. Notwithstanding this, at the Customer's request the test samples can be destroyed after completion of the tests. The test samples will be stored until the destruction as long their condition with a storage and according to the state of technology permits an evaluation, a maximum however of three months. After this time test samples shall be destroyed at the Customer's costs; this applies in particular with the necessity of a special disposal owing to statutory regulations. Sufficient documentation shall be prepared of the test samples. The final treatment of the test samples must be agreed within the framework of the commissioning before the start of the tests.
In the event that a mark approval is granted the testing body shall stipulate whether the test sample is stored as storage sample for the Customer by EUROFINS or has been handed over to the Customer for storage marked and sealed. Storage samples or documentation which are handed over to the Customer are to be made available by it to EUROFINS upon request free of charge at short notice. If the Customer is, no matter for what reasons, and upon request not in the position to make storage samples and/or documentation available then each liability claim for property damages and financial losses of the Customer against EUROFINS results from the respective test and certification shall lapse. If in the event of a certification the type of construction of the storage sample does not allow a storage either at EUROFINS or at the Customer or if for other reasons the storage of the storage samples is waived then a detailed documentation of the storage samples is to be created for the account of the Customer to the extent that all aspects from the documentation which are relevant for tests can be seen.
The costs for the storage in warehouses of EUROFINS and a possible subsequent disposal or the pick-up or return shipment of the test samples must be borne by the Customer. If the Customer does not pick up the test samples despite a written notification or if it refuses or waives the acceptance then the test samples shall be scrapped for its account after a waiting period of 2 months. EUROFINS shall not be liable for possible damages to the test samples through the tests as well as through burglary, theft, fire, water, transport or other events of force majeure. This shall also apply accordingly to documents of the Customer which were made available.
The storage duration of the documentation is 10 years after the lapse of the quality mark certificate; insofar as not otherwise regulated by statutory provisions.

3. Certification system

3.1 Basic requirements

Test reports can be made the basis for assessments within the framework of the certification which stem from laboratories that have been accredited according to the rules of DIN EN ISO/IEC 17025 or work verifiably so that quality and acceptance of the test laboratory exist. The certification body of EUROFINS primarily carries out assessments and certifications based on the test reports of EUROFINS, which are subject to the same QM system. In addition, test reports of other test laboratories can also be used for the assessment within the framework of the certification, respectively by complying with the stipulations applicable in the individual certification schemes. Test reports, which are to serve as basis for a certification, may not be older than 1 year at the time of the certification and are not based on invalid standards. The offered certification procedures, the process as well as scheme specific requirements are published on the Eurofins webpage. Additional information is provided from the certification body on request.
The conditions for the conclusion of a contract described in section 2.1 with the simultaneous confirmation of recognition of the PZO, as well as the terms and conditions of the EUROFINS apply. If the certification of a quality management system was requested for the manufacturer of medicinal products pursuant to DIN EN ISO 13485 or a quality assurance system in accordance with Annex II, V or VI of the 93/42/EEC directive, the "Zertifizierordnung Managementsysteme" also apply. In the event of an extension to certification in accordance with Appendix III of Directive 93/42/EEC, the application should be sent five months in advance if possible, but at the latest four months prior to expiry of certification, in order to ensure the certification status can be maintained without interruption. If differences of opinion between the manufacturer, or its European authorized representative, and the Notified Body arise in relation to the application of the classification criteria for medical devices pursuant to Appendix IX of Directive 93/42/EEC, the Notified Body must submit the issue to the responsible federal office, which will then make a decision.
The authorization to use the certificate shall only apply to the certificate holder based on the product named in the certificate, the product plant named in the certificate and the scope covered by the QM system. An assignment of a certificate from the certificate holder to third parties is not allowed, as well the use of the certificate respectively the mark by third parties. Product certificates can be limited to certain contingents and lots. A limitation of the certificate validity is permitted in special cases.
Fees are to be paid by the certificate holder for the participation in the certification system and the issue of certificates in line with the price list of EUROFINS. The certification body of EUROFINS can stipulate that both the certification fees as well as the administrative/approval fees are paid in advance before the certification. For GS-Mark approvals is in addition to pay an annual fee for the period of validity of the certificate.
Regulations to the statutory product liability of the customer and the Commercial General Liability Coverage of EUROFINS are described in section 2.1.
The certification body of EUROFINS reserves the right to publish the certified products and QM systems for the information of the accreditation agencies, supervisory authorities and consumers and other interested authorities. This includes the publication of illegally used as well misuse of GS-Mark approvals. This does not require any separate consent of the certificate holders. In the function as "notified body" or "authorised body" information about issued certificates which were declared invalid and withdrawn can continue to be forwarded without the consent of the certificate holder (e.g. to authorities, market authorities, other notified bodies). Based on § 18 MPG (Medical Devices Act) in connection with the DIMDI regulation (DIMDI - Database-supported Information Systems on Medical Products of the German Institute for Medical Documentation and Information), the Notified Body is still obliged to report all refused, issued, revoked, amended, suspended or restricted certifications in accordance with Directive 93/42/EEC as well as the associated test reports to the medical product reporting system of the DIMDI and other Notified Bodies. According to Directive 93/42/EEC, Appendix III, Section 7.2, other Notified Bodies are authorised to receive a copy of the EC-type examination certificate and/or amendments thereto. The appendices to these

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certifications will be made available to the Notified Bodies in the event of a justified request and after the manufacturer has been notified.

3.2 Types of certificates

With the satisfaction of the contractual agreements the certification body of EUROFINS shall issue the following certificates:

- GS-Mark approvals according to the Product Safety Act (ProdSG) as "approved body" (GS-Body)
- Product certificates according to the international IECEE agreement (CB Scheme) as National Certification Body (NCB)
- Mark approvals for private quality marks of EUROFINS (Eurofins-BG-Mark ("Bauart geprüft"))
- Conformity assessments as "Notified Body" under the Annex III of the Radio Equipment Directive 2014/53/EU
- Assessment and monitoring of quality management systems as "Notified Body" under the Annex IV of the Radio Equipment Directive 2014/53/EU
- FCC Grants as conformity assessment body (CAB) within the framework of the agreement between the EU and the United States of America (MRA)
- Innovation, Science and Economic Development Canada - REL Certificates as conformity assessment body (CAB) within the the CETA agreement
- Certifications for quality management systems of manufacturer for medical devices acc. DIN EN ISO 13485 (validity maximum of 3 years)
- EC-conformity certificate acc. EC directive as "Notified Body" acc. Medical Devices Directive 93/42/EEG, annex II, III, VI, V (validity maximum of 5 years) and annex VI (without validity)
- Eurofins CoTaA (Certificate of technical assessment and acceptance) for the attestation of conformity with standards.

The certification schemes according to which the EUROFINS certification body works are published on the EUROFINS Web page (https://www.eurofins.de/ipt).

Conformity certificates alone do not entitle to use a quality mark of EUROFINS. They must, if quality marks of EUROFINS are to be used, always be combined with a separate quality mark approval. Advertising with the conformity certificates is only possible with the explicit, written consent of the certification body of EUROFINS.

GS-Mark or Eurofins-BG-Mark approvals are only issued if an initial factory inspection was carried out together with the type approval which in the end allows one to expect a product quality which is equal to the presented model. At the same time a periodically recurring inspection of the product manufacturing by EUROFINS is the pre-requisite for this. Alternative and/or supplementary measures for inspection the production according to the principle resolutions of ZEK can be applied after stipulation by the certification body.

3.3 Obligations of the customer from certifications

With the certification agreement, the customer agrees to the following:

- Meet the certification requirements and the requirements of the certification scheme,
- Meet the product requirements, if the certification applies to a current production,
- Meet of all measures for the implementation of evaluation and monitoring,
- Claims only in the scope of certification,
- Use the certification not in a misleading way or a way that could discredit the EUROFINS certification body,
- Meet the requirements for using the product certification in documents, brochures or promotional material, when using mark of conformity, etc., as well as discontinuation of any use of promotional materials in case of suspension, withdrawal or termination of the certification, as well as to take all measures required by the certification scheme,
- Make no reference to the certification of its management system that could indicate that the certification body has certified a product/service or applies to activities, which fall outside the scope of the certification,
- Duplicate of certification documents only in their entirety, and according to the certification scheme.

If the Customer has filed an application for a product certification in advance at another stated body then he is prohibited from submitting an application which refers to the same product at EUROFINS. The certificate holder is obliged to archive certificates, documents or reference samples, which have been handed over to it for storage within the framework of conformity certificates or quality mark approvals, for the duration of the statutory storage periods, at least however 3 years, and upon request of the certification body of EUROFINS make these available free of charge.

The certificate holder is obliged to regularly monitor the production of the certified products for correspondence with the approved test samples and in particular to properly carry out the stipulated measures or measures required by the certification body of EUROFINS for quality assurance. In the framework of the GS-Mark certification, the customer is obliged to retain at least two samples for the duration of the validity period of the certificate to ensure the quality and verifiability in factory inspections.

The certificate holder shall immediately report planned changes or changes made by it to the product compared with the design which was approved based on the test sample or planned or carried out changes in the certified QM system to the certification body of EUROFINS, as well as all other changes with regard to the fulfilment of the certification requirements (e.g. changes to production method, ownership, key personnel, etc.). The further approval depends on the proof of the manufacturer about the compliance with the safety provisions or by an additional test or an additional audit by EUROFINS. If necessary, a complete recertification of the product/quality system is required.

If defects are determined in the first test or in follow-up tests of a submitted product and if the Customer has already delivered products which correspond with the test sample then the certification can only be issued for the newly submitted, changed test sample if the manufacturer introduces a new designation for the new type.

The certificate holder shall report intended relocations of assessed factories or the intended assignment of its company to another company or another company owner to the certification body of EUROFINS in time.

The certificate holder must allow the requirements stipulated in the Product Safety Act (ProdSG) under section 2 (for GS-Mark approvals also section 5) to apply to it.

The certificate holder must record and archive all complaints relating to its certified product and initiate appropriate measures. Upon request of the certification body of EUROFINS it must make these documents available immediately free of charge and inform it of the measures it took to remedy justified complaints.

The certificate holder undertakes to correct subsequently determined, serious safety defects to products, which bear a CE labelling or a quality mark of EUROFINS owing to a type test certified by EUROFINS, immediately and to take suitable measures in order to minimise damages in the market. In any case it must suspend the bringing into circulation of the labelled products directly and inform the certification body of EUROFINS. EUROFINS is entitled or obliged to partly forward the information of which it has become aware, owing to statutory or official reporting duties. This or the granting of an approval, a certificate, etc. do not release the Customer from its obligations as manufacturer; this also includes reporting duties towards authorities.

The Customer further declares that it agrees that, upon request of the accreditation body of EUROFINS, of the regulatory authority or market authority, information, documents, etc. both relating to the contract as well as the object of the contract may be forwarded to it by EUROFINS, for the whole period of storage (see section 2.4). This in particular comprises a list of certified products and documentation and information about the certification application as well as information about the conducting of audits, testing and certification, the granting, refusal and withdrawal of approvals, certificates, etc., occurring incidents and risks in the indirect or direct connection with tested products. The accreditation body of EUROFINS and/or the regulating authority as well as Eurofins by itself, explicitly reserves the right to carry out witness audits in the plants of the Customer and its sub-contractors or to provide co-auditors. The Customer shall permit this and oblige its sub-contractors accordingly.

In addition the following conditions and obligations apply to Canadian certifications: ISED (Innovation, Science and Economic Development Canada) will record the details of all certifications in the Department's Radio Equipment List (REL) based on the notification received from the CB by electronic filing. Certified equipment shall not be distributed, leased, sold, or offered for sale in Canada before the details of its certification have been added to the REL. The EUROFINS certification body pays the necessary REL listing fee on behalf of the certificate holder and then charges the fee to the applicant. The label requirements according RSP-100 apply.

ISED can require the affected certificate holders to provide a copy of the original certification submission which includes a technical brief. Certificate holders shall retain copies of their original certification submission for a period of ten years.

Where, as a result of post-certification audit or other information obtained by the EUROFINS certification body, a certified device fails to meet this procedure or the applicable technical requirements, or where there is reasonable evidence that a certified device is creating electromagnetic interference or not operating in accordance within the parameters described on the Certificate, the EUROFINS certification body will inform ISED and the certificate holder will be required to take remedial action.

The certificate holder shall make provision to always have production samples available upon request by the EUROFINS certification body or by the ISED, for auditing purposes. For this, appropriate samples are to be kept. In the event of an investigation of non- compliance, the certificate holder will be asked to provide, to the EUROFINS certification body or ISED, records of the quality control process and any relevant information that would help to identify the cause and extent of the non-compliance. It is expected that all certificate holders will be able to demonstrate a quality control process used for production inspection and testing in accordance with good engineering practices. If a product fails to comply with the applicable requirements during an audit conducted by the EUROFINS certification body, the EUROFINS certification body immediately notifies the ISED. The regulations in section 3.5 apply.

3.4 Rights of the customer from certifications

The certificate holder is entitled to affix the quality mark of EUROFINS, which was released to it for use, on its products and to use it product-related in printed matter, etc. and to refer to the granted quality mark approval in advertising measures. It is not permitted to use certification marks to laboratory test reports, inspection reports, certificates or similar documents, nor is it permitted to publish misleading, inadmissible information or apply it to packaging, supplementary information or the product itself. The agreement on the usage of symbols also applies to the certificate owners of certified management systems.

The mark holder is only entitled to use the quality mark released to it for use for advertising measures, etc. during the period of the granted mark approval – not however after the mark approval according to Point 3.5 has lapsed or was declared invalid. Repro template of the quality mark are available for creating printed matter which can be acquired by the Customer together with a printing licence A mistake about the granted quality mark approval must however be excluded.

The quality mark approval shall apply to the full product which is ready for use. In special cases the certification body of EUROFINS can allow the certificate holder to take the products which have been issued quality marks of EUROFINS apart for shipment to the extent that this normally happens for the installation of the product in a plant.

If products with the same construction, for which a quality mark approval is available, are to be brought into circulation under another mark of origin or name and if applicable also with a new type designation then a Co-Certificate (Co-License) or a certificate extension (Multilisting) can be issued by the certification body. Insofar as restrictions exist in this respect through state or comprehensively regulated certification processes then these are to be complied with.

The certificate holder may only forward test reports and similar items with the full wording by stating the date of issue. However, a publication or reproduction requires the prior written consent of the certification body of EUROFINS.

3.5 Deletion and invalidity declaration of a certificate

A certificate shall lapse if

- the certificate holder waives the certificate and reports the termination of the certification body to EUROFINS in writing
- the period of validity stated in the certificate has expired and it was not extended (GS-certificates, Eurofins-BG-certificates and QM system certificates have a maximum validity period of 5 years)
- the contract with EUROFINS is terminated by one of the contractual parties by observing the periods of notice,
- the certificate holder goes bankrupt or an application for the opening of bankruptcy proceedings directed against it is rejected return unsatisfied,
- the provisions upon which the certificate is based (including the accreditation regulations relating to this certificate) were changed or other provisions, e.g. owing to changed use, are to be applied.

The validity of the certificate can however be extended if it is determined through a follow- up test conducted at the costs of the certificate holder within a set deadline that the approved products also comply with the new provisions.

A certificate can be terminated or declared invalid by the certification body of EUROFINS, in particular if

- owing to facts which could not be recognised without a doubt at the time of the test, the further use of the certificate and if applicable, a resulting CE labelling or a quality mark is not feasible with regard to its informative value on the market,
- the requirements, which are applicable as pre-requisite for the granting of the certificate were not satisfied, the product or the product category was allocated to the false type of product, for which other provisions are to be applied, the product or the product category was allocated to a false class and insofar a false declaration was submitted,
- the product or the product category no longer satisfies the fundamental requirements to the extent that consumers, users or other third parties are exposed to significant risks or the product does not satisfy the intended use as stated by the manufacturer and these defects are not remedied within a stipulated or reasonable deadline,
- defects to the product which were not recognisable or could not be determined during the test are determined subsequently and these are not remedied by the manufacturer in the short-term,

- misleading or otherwise inadmissible advertising is carried out with a conformity certified or the quality mark,
- an examination of the product marked with a quality mark of EUROFINS or with a CE labelling by using the EUROFINS logo and/or the code number of EUROFINS shows serious defects,
- a product marked with the CE labelling by using the EUROFINS logo and/or the code number of EUROFINS or a quality mark of EUROFINS does not correspond with the approved type,
- defects determined during the regular audit according to Pt. 4 are not remedied by the Customer within a reasonable deadline stipulated by EUROFINS,
- the certificate holder refused or does not enable the inspection of the production and test equipment or of the warehouse by the authorised agent of EUROFINS or the withdrawal of products for audit and does not allow a proper execution of the production control audits according to Pt. 4 despite a written request by EUROFINS within 4 weeks,
- the manufacturer does not permit or impedes the agreed audits of its QM system by the "notified body",
- due fees are not paid by the certificate holder within the set deadline after a reminder. If the fees do not refer to a certain certificate then the certification body of EUROFINS, shall decide which certificate the measure show cover.
- the certificate holder of Canadian certification takes no corrective action, as required by section 3.3. In addition, the product will be removed from the REL and the certificate holder must take the illegal product out of operation and should no longer sell or distribute it in Canada.

The certification body of EUROFINS shall give the Customer the opportunity to present its opinion before declaring the invalidity of a certificate within 14 days or an individual determined time, unless such a hearing is not possible owing to the urgency of the measures which are to be taken.
The certification body of EUROFINS may publish the invalidity declarations at its own choice.
The certificate holder will automatically lose the right to continue to affix the products listed in the certificate with quality marks of EUROFINS if the certificate has lapsed through termination on a certain date or has been declared invalid at short notice. The original certificate is to be returned to the certification body of EUROFINS.
The certification body of EUROFINS shall not be liable for disadvantages, which the Customer suffers from the non-issue, the termination or the invalidity declaration of a certificate. The certification body of EUROFINS is entitled to inform the supervisory authorities, the accreditation agencies, the "notified bodies", "authorised bodies" and the licensing authorities about the invalidity declaration which it has announced.
There is no "period of validity" for expertise. Expertise shall remain valid as long as the conditions which led to the expertise are unchanged. In case of changes then it ist he responsibility of the manufacturer to stipulate whether a new or changed expertise is necessary. Approvals of quality assurance systems are subject to a period of validity which is stipulated for the certificate.

3.6 International type approvals

International type approvals enable the Customer to legally place the product on a stated market based on certificates of the relevant national approving authorities.
Depending on the valid legislation of the respective country with the regard to the filing of an application for a type approval these certificates can contain the following:

- National type approval certificate with type approval number,
- National registration number based on a manufacturer's declaration (or through its authorised agent),
- Legally valid letter which notifies that the product can be used at liberty without having to meet any requirements (so-called clearance certificates),
- "Exception permit" which is granted by the national approving authority,
- Provision of local representatives in selected countries (liable to costs, upon request).

The EUROFINS „International Approval"-Service is carried out by customer service staff. It comprises the compilation and completion of the required documents and submission of these to the national approving authorities, i.e. the coordination and acceleration of the planning of the approval process. As a result of which a letter is delivered in the form it was received from the national approving authority as well as instructions for labelling and period of validity. An approval service within the scope of medical products is excluded.
The EUROFINS „International Approval" service does not include:

- incurred travelling expenses (travelling expenses require the prior coordination with the Customer),
- Fees for translations,
- additionally incurred costs for courier services for the shipment of test samples and/or documents,
- Appointment of local representatives in the respective countries if this is stipulated in line with the provisions of the national approval regulations (a close cooperation with the local authorised agent is essential for a short processing time),
- the involvement of a notified or approved body,
- Agreements under contract law and regulations with the local representatives are the responsibility of the applicant insofar as the local representative is not provided by order of Eurofins.

In the event that no certificate has been received from the national approving authority by taking into account the delays calculated in the offer or for reasons which are not due to EUROFINS, all additionally necessary efforts to receive a certificate shall be invoiced separately after prior coordination.
The Customer must provide all documents which are necessary for the approval of the product. The technical documents of each model are necessary for a more efficient flow of the EUROFINS "International Approval" service. The following documents are usually requested by the approving authority:

- Test report(s) in English or the national language,
- Technical description of the appliance preferably in the national language or in English,
- Function description,
- Manual, in English or national language (occasionally necessary),
- Block circuit diagrams, electrical circuit diagrams, PCB layout, parts lists,
- Photos in colour (product exterior and interior)
- Type plate (label example, manufacturer or applicant),
- additional certificates and declarations of conformity (English and national),
- customary power of attorney for the trade, which authorises EUROFINS to carry out the approval process,

EUROFINS reserves the right to invoice up to 100% of the total invoice at the time when the order is confirmed. The remaining amount is to be paid in line with the progress of the project. Incurred costs of sub-contractors or authorities will be invoiced by EUROFINS immediately. In the cases in which the execution of the „International Approval"-Services is not possible and the reasons for this cannot be attributed to EUROFINS, EUROFINS reserves the right to invoice up to 50% plus external costs.

The periods of time for each country as stated in the offers are estimates based on experience. The settlement shall begin at the time at which all relevant documents were submitted to EUROFINS by the Customer. The actual throughput time depends to a large extent on the approving authorities. We reserve the right to integrate sub-contractors. No guarantee is assumed with the submission of an offer that an approval can be reached in all countries. Additional agreements shall only apply in a written form.

4. Recurring inspections

4.1 Inspection of the product production

In order to assure and maintain a constant product quality of the certified products with Eurofins-BG-Mark and GS-Mark approvals according to the Product Safety Act (ProdSG) or within the CB Factory Surveillance Service in accordance to IECEE 03 (CB-FSS), EUROFINS carries out regular audits of the production and test equipment. As a rule an annual audit can be assumed, however the certification body of Eurofins can also stipulate reduced cycles.
In addition, EUROFINS can inspect the products, factories and warehouses stated in the certificate (with foreign certificate holders also the warehouses of the importers or the German authorised agents and the branches) at all times without prior announcement. It can remove products, for which a certificate has been issued, free of charge for control tests and also carry out examinations in factories and warehouse. In exceptional cases tests can be carried out on a test sample, which is representative for the serial production, in order to monitor the consistent production quality. EUROFINS can commission other independent and qualified authorities to carry out the follow-up tests in its name. Alternative or supplementary measures for inspection the product production can be applied for Eurofins-BG-Mark and GS-Mark approvals according to principle decisions of the ZEK in its respective actual form.
For the use of the CB Factory Surveillance Services, the manufacturer and applicant bear the responsibility according to IECEE OD-4003 and IECEE OD-4003-SR-EU (if applicable), i.e. the manufacturer is responsible for

- adequate control over all subcontractors and out-workers,
- clear identification and segregation of any non-conforming product,
- maintaining appropriate records to demonstrate conformance with FSS (at least: Incoming inspection of components (including Certificates of Conformity), Routine Tests, Functional checks and calibration of test and measuring equipment, Customer complaints and corrective action)
- ensuring that all purchased materials, components and subassemblies comply with specified requirements,
- inspection at appropriate stages of manufacture (production control, inspection and routine tests) to ensure that piece-parts, components, subassemblies, wiring runs, workmanship, etc. are in accordance with the sample for which certification was granted,
- conducting functional checks at intervals which will allow previous production to be re-tested if incorrect functioning of the test- and measuring equipment used for safety (routine) tests is detected,
- ensuring that the Certification Mark is applied only to products that comply with the requirements,
- calibrating test and measuring equipment used for determining the safety of the products being manufactured,
- proper identification and storage of components, materials, sub-assemblies and finished products,
- taking care of corrective actions to any unsatisfactory finding found during the factory surveillance,
- recording any technical complaint regarding the certified product,
- notifying the Certification Body about constructional changes which may affect compliance with the relevant standard, prior to its implementation on certified products.

The same is valid for the performance of factory inspections within the Eurofins-BG-Mark and GS-Mark scheme. In addition, the manufacturer is responsible for

- performing Periodic Product Verification Tests (PVT) on samples taken randomly from the production line,
- monitoring all procedures used in the manufacturing- and control process of certified products (Manufacturer's self-assessment)
- ensuring that re-examination samples can be selected by the inspector from the production line or from stock (if required by the certification Body).

4.2 Monitoring of QM-Systems

The EUROFINS QM Certificate of EUROFINS can include confirmation of RED-directive conformity by EUROFINS as notified body. Only the EUROFINS QM certificate (approval) as documentation of the conformity with the directives entitles the Customer with the CE labelling of the products produced under this QM system to use the Brussels code number of EUROFINS. Attention is to be paid that the EC conformity certificates which are possible required by the directives are available. The pre-requisite for issuing and maintaining the EUROFINS QM certificate is the assessment of the QM system for the agreed scope and the agreed test basis in the form of a certificate audit which was completed with positive results, monitoring audits which are to be conducted annually and repeat audits which are to be carried out successfully in order to extend the certificate. The EUROFINS QM certificate applies for respectively 3 years.

4.3 Costs for recurring inspections

The costs for carrying out the factories- and follow up inspections and the QM system audits are invoiced to the certificate holder according to the price list.

5. Market control

The certification body of EUROFINS can remove products, which are marked with a quality mark of EUROFINS or with a CE labelling by using the EUROFINS logo and/or the code number of EUROFINS from the market at all times for a control test.
In case deviations from the approved type or defects are determined during the control test the certificate holder shall receive a written report about the results of the audit and must assume the total costs incurred through the follow-up test.

6. Infringements against the test and certification system

The certification body of EUROFINS is entitled, with determined culpable infringements of the Customer against the test and certification system of EUROFINS in addition to the invalidity declaration of the certificate according to Pt. 3.5 to also request a conventional penalty up to an amount of € 100,000.- for each infringement by the certificate holder. This applies in particular in case of unlawful use of quality marks of EUROFINS, i.e. if no certification is carried out or a certificate has not yet been issued or if a quality mark of EUROFINS is used although the certificate has been declared invalid by the certification body of EUROFINS or if inadmissible advertising is carried out with quality marks of EUROFINS or with conformity certificates.

If the Customer does not satisfy the obligations according to Point 3.3 then the certification body of EUROFINS can take the corresponding measures itself. These include e.g. information of the users to minimise damages in the market and notification to the supervisory authorities, public authorities that are entitled to issue notifications, accreditation bodies, "notified bodies" and “recognised bodies”.
EUROFINS reserves the right to demand reimbursement of expenses from the Customer which are incurred to EUROFINS owing to the infringement of the Customer against the test and certification system. Such expenses are in particular costs for comparable tests of certified products with products which are taken from the market by order of EUROFINS or are served by official authorities, companies, private persons, etc. and research which is necessary within the framework of comparable tests.
Other measures which are necessary within the framework of comparable tests and research such as factories inspections, shipping controls, control of warehouse stocks, etc. comparable tests and research as well as other measures are charged according to required time according to the respective valid remuneration regulations of EUROFINS.
In addition, the certification body of EUROFINS reserves the right to terminate the „general contract“ with immediate effect, to declare further certificates existing for the Customer to be invalid and/or to accept no new certification requests of the customer for a specific period of time, insofar as EUROFINS can see its trust in the loyalty to the contract and the reliability of the Customer as shaken owing to the infringement of the Customer against the test and certification system.
In the event of proceedings pursuant to Appendix IV of the Directive 93/42/EEC, a certificate can be refused, revoked, suspended or restricted, without complying with a deadline but after providing the customer with an appropriate hearing, if:

1) misleading or other inadmissible advertising is used with the certificate or the certificate is misused, or if the certificate is used in a manner that discredits the certification body;
2) legal provisions or official stipulations are not or no longer complied with;
3) the certification body determines that a certificate should not have been issued;
4) the customer does not settle claims of the certification body despite reminders. All certificates can also be revoked if only partial payment is received;
5) the certificate owner rejects in writing a change to the general terms and conditions or this certification system within a period of six weeks following entry into force or within the period provided for them to take notice thereof;
6) the legal or normative requirements or the technology rules change, upon which the certificate is based unless the certificate owner can prove that the system complies with the new requirements/rules within a specified period through a renewed examination by the certification body;
7) the customer breaches the general terms and conditions or certification system of the certification body as long as this is not due to slight negligence or does not relate to a significant breach, or
8) the customer requests revocation, suspension or restriction of the certification in writing.

Before a decision is made regarding the refusal, restriction, suspension or revocation of certificates in accordance with Appendix III and IV of Directive 93/42/EEC, the Notified Body must provide the manufacturer with a hearing, unless such a hearing is not possible as the decision in question needs to be made as a matter of urgency. The hearing must be made within 14 days or a reasonable, individually laid down period.

7. Complaints and appeals

The Customer or certificate holder can file a complaint against the operation or an appeal against decisions of the certification body of EUROFINS with which it is not satisfied within the framework of the conducted test and certification process. This can be sent directly to the certification body, customer service or quality department over the Eurofins webpage. The certification body gives the complainant detailed substantiation for its decision. If the given substantiation of the certification body is not acceptable for the complainant then it is entitled to file a complaint at the management and/or the strategic committee. In any case, the complaint or appeal of the customer has no influence on other testing and certification projects and is not interpreted to a disadvantage.

8. Entry into force and change

The test and certification system shall come into force on 01.01.2019. They shall cease to apply after the establishment of new test and certification system with a transitional period of 6 months. The Customers or certificate holders shall be informed specially about the change to the test and certifying system.

Rechtsverbindlich ist die deutsche Fassung.
The German wording is binding.

Stand: 12.12.2018

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