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Shirley® Publicly Available Information for ISO/IEC 17065 - Product Conformity Certification

1. Certification schemes
2. Granting Certification (Initial Certification)
3. Refusing Certification
4. Maintenance of Certification
5. Suspension of Certification
6. Withdrawing Certification
7. Extending the scope of Certification
8. Reducing the scope of Certification
9. Shirley® fees and status
10. Rights and duties of applicants and clients
11. The use of the Shirley® name and certification mark / numbers
12. Procedures for complaints and appeals
13. Requests for information
14. Information provided to third parties

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1. Types of certification schemes

Shirley Technologies (Europe) Limited, trading as Shirley®, is a Notified Body, accredited by the Irish National Accreditation Board to ISO/IEC 17065:2012 (accreditation number 6033), to provide product conformity certification to
the following Directives and Regulations:

PPE - The Personal Protective Equipment Regulation, (EU) 2016/425
Shirley® is Notified Body 2895 for Regulation (EU) 2016/425 on Personal Protective Equipment, appointed by the Department of Enterprise, Trade and Employment. Shirley® is appointed for:
Module B: EU type-examination
Module C2: Supervised product checks at random intervals
Module D: Quality assurance of the production process

CPR - The Construction Products Regulation, (EU) No 305/2011
Shirley® is Notified Body 2895 for the Construction Products Regulation (EU) No 305/2011, appointed by the Department
of Housing, Local Government and Heritage. Shirley® is appointed for:
Annex V: FPC Certification Body (AVCP) System 2+
Annex V: Product Certification Body (AVCP) System1

MED – The Marine Equipment Directive,2014/90/EU

Shirley® is Notified Body 2895 for the Marine Equipment Directive 2014/90/EU implemented by the European Union (Marine Equipment) Regulations 2017, appointed by the Marine Survey Office (MSO) of the Irish Maritime Administration. Shirley® is appointed for the approval of Fire Protection Equipment:

Module B: EC Type Examination
Module D: Production QA
Module E: Product QA

Details of the Shirley® scope for each scheme can be found on the INAB schedule of accreditation, available from:

https://www.inab.ie/inab-directory/certification-bodies/product-certification/shirley-technologies-europe-limited.html

2. Granting Certification (Initial Certification)

In general terms, product certification is granted when Shirley® concludes that:

- the product and any relevant documentation complies with the requirements of the legislation;
- the requirements of any specified Designated Standard, Technical Specification or International Instrument are met;
- any relevant approved guidance is complied with.

Certification of products manufactured is granted when Shirley® concludes that:

- the product has been selected by Shirley® or its representatives successfully;
- the selected product meets the requirements of the legislation;
- any specified Designated Standard, Technical Specification or International Instrument are met;
- any relevant approved guidance is complied with;
- the selected product matches the original approved model or type.

Certification of the client's system for controlling the production or product is granted when Shirley® concludes that:

- if relevant, the performance of the product has been established by Shirley® based on type-testing;
- the production and other relevant sites have been successfully audited by Shirley®;
- the manufacturer's factory production control system ensures conformity of the manufactured product with the declared performance or approved model;
- any nonconformities are cleared to the satisfaction of Shirley®.

Certificate validity

- PPE Module B Certificates are issued with a validity of a maximum of 5 years.
- PPE Module C2 approval reports are issued with a validity of 1 year.
- PPE Module D Certificates are issued with a validity of 3 years.
- CPR System 1 and 2+ Certificates are issued with no expiry date.
- Marine Equipment Module B Certificates are issued with a validity of a maximum of 5 years.
- Marine Equipment Module D and E Certificates are issued with a validity of 3 or 5 years.

3. Refusing Certification

The decision to refuse certification is made by one of the Shirley® Decision Makers. For product certification and product selection and testing, this may occur when:

- the product does not meet the requirements of the legislation or the relevant standards and specifications;
- the product no longer conforms with the original approved model;
- the specified technical documentation does not meet the requirements of the legislation or the relevant standards and specifications.

For factory production control systems, this may occur when:
- Shirley® concludes that the quality system cannot ensure that the production conforms with the approved or declared model.

4. Maintenance of Certification

For any major nonconformity or other situation that may lead to suspension or withdrawal of certification, one of the Shirley® Decision Makers will determine whether certification can be maintained.

For product certification

Certification is maintained provided that the client complies with the conditions of certification:

- The address of the client is that which appears on the certificate;
- The certificate has not been transferred or assigned to another organisation;
- The certificate has not been lost, duplicated or altered without the authorisation of Shirley®;
- The client is not promoting certification for products or services other than those covered by the certificate;
- The client is not claiming compliance with other standards through the use of the certificate or audit report other than that appearing on the certificate;
- Certificates or promotional materials associated with them are not promoting erroneous or misleading information;
- The client investigates complaints associated with the certified products. Records of such complaints, and actions taken, are kept by the client and are made available to Shirley® when requested;
- Production is limited to the site(s) notified to Shirley® at the time of certification;
- Any changes to the product or quality manual / quality plan are immediately notified to Shirley®;
- For Category III PPE, the client maintains Module C2 or Module D approval with a Notified Body.

Renewal of product certification must be requested by the manufacturer before the Certificate expires. If required, declarations and relevant retesting must be submitted.

For factory production control systems

Surveillance activities include on-site or remote auditing of the client's management system. Surveillance audits are on-site or remote audits, but are not necessarily full system audits.

Certification is maintained provided that the client complies with the conditions of certification:

- The address of the client is that which appears on the certificate;
- The certificate has not been transferred or assigned to another organisation;
- The certificate has not been lost, duplicated or altered without the authorisation of Shirley®;
- The client is not promoting certification for products or services other than those covered by the certificate;
- The client is not claiming compliance with other standards through the use of the certificate or audit report other than that appearing on the certificate;
- Certificates or promotional materials associated with them are not promoting erroneous or misleading information;
- The client permits ongoing surveillance and access to documentation and records, and access to the relevant equipment, location(s), area(s), personnel and client's subcontractors;
- The client investigates complaints associated with the certified products or services. Records of such complaints, and actions taken, are kept by the client and are made available to Shirley® when requested;
- The client allows participation of observers during surveillance audits when requested.

For factory production control certificates with an expiry date, a re-assessment of the system must be completed by Shirley® before the certificate can be re-issued. This re-assessment audit will normally be conducted at least 3 months before the certificate expiry date to allow for closure of any corrective actions and the reissue of the certification.

5. Suspension of Certification

Suspension of certification occurs when Shirley® believes that:

- the product no longer meets the requirements of the legislation or relevant standards and specifications;
- misuse of the certification has seriously breached the conditions of certification;
- the client's quality system has persistently failed to meet certification requirements;
- the client has not enabled surveillance audits or recertification audits to be conducted at the prescribed intervals;
- the certified client has requested the suspension of a certification;
- there is a dispute over certificate ownership.

The client will be required to:

- Cease promoting their certification on advertising material;
- Submit corrective action, if appropriate;
- If relevant, allow access to the Shirley® audit team to conduct an investigatory audit, if this is deemed appropriate, prior to lifting the suspension.

Suspension is limited to a maximum period of 6 months before certification withdrawal commences. If certification is suspended, the client's certification is temporarily invalid:

- Certified product must not be sold or released;
- The client must discontinue its use of all advertising matter that contains any reference to the certification. Shirley® will restore the suspended certification if the issue that has resulted in the suspension has been resolved.

Where evidence is submitted or audits performed, one of the Shirley® Decision Makers will determine whether certification can be reinstated, or whether the scope of certification or product performance or classification should be limited or reduced, or certification should be withdrawn.

6. Withdrawing Certification

Shirley® may withdraw certificates in the following cases:

- The client informs Shirley® in writing that the certification is no longer required, or that they do not wish to maintain the validity of the Certificate;
- Wind-up of the client without a legal successor;
- Unauthorised use of the Certificate;
- The client is in breach of the certification agreement;
- The product no longer conforms to the original approved model;
- Production has been moved to a different production site without the approval of Shirley®;
- The client does not accept scheduled surveillance or re-assessment audits;
- A serious non-conformity reoccurs in two consecutive audits;
- Non-conformities raised in the audits are not corrected within the time limit prescribed by Shirley®;

- The maximum period of a suspension has ended and corrective actions required were not carried out.

Complaints can also result in certification withdrawal and will be judged by one of the Shirley® Decision Makers on a case-by-case basis.

Upon withdrawal of certification, the client must discontinue its use of all advertising matter that contains any reference to the certification.

7. Expanding the scope of Certification

A client wishing to expand the scope of certification must submit an application with details of the requested extension. Shirley® will review the application and any submitted documentation. Additional product tests may be necessary. An additional audit may be necessary, or it may be combined with a surveillance audit.

8. Reducing the scope of Certification

The scope of certification may be reduced in the following circumstances:

- At the client's request;
- Following suspension of the certification;
- If the client has persistently or seriously failed to meet the requirements for those parts of the scope;
- If the product no longer meets the declared or tested performance or classification.

9. Shirley® fees and status

Shirley® is an independent certification organisation, owned by its management and staff. Fees are charged for all certification work.

10. Rights and duties of applicants and clients

For certification of products, the applicant must not have submitted the same product for certification to any other notified bodies.

For certification of product and production quality control systems for specific products, the applicant must not have applied to another notified body for approval of the system for those products.

PPE Module B

Clients must place the Shirley® name, notified body number and address on the user information for any certified product.

Clients must include the Shirley® name, notified body number and address on their Declaration of Conformity.

PPE Module C2 and D

Clients must place the Shirley® notified body number on the PPE, beside the CE mark, for PPE manufactured during the validity of the certification.

Clients must place the Shirley® name, notified body number and address on the user information for any certified product. Clients must include the Shirley® name, notified body number and address on their Declaration of Conformity.

CPR System 1 and 2+

Clients must include the Shirley® name and notified body number on the Declaration of Performance. Clients must place the Shirley® notified body number on the CE label.

Marine Equipment Module B

Clients must include the Shirley® name, notified body number and address on their Declaration of Conformity.

Marine Equipment Module D/E

Clients must place the Shirley® notified body number on the marine equipment, beside the Wheelmark, for marine equipment manufactured during the validity of the certification.
Clients must include the Shirley® name, notified body number and address on their Declaration of Conformity.

11. The use of the Shirley® name and certification mark and notified body number

For the PPE, CPR and Marine Equipment certification schemes, the Shirley® certification mark is our notified body number, 2895. Information and requirements for the use of the Shirley® name and notified body number is included in our Certification Terms and Conditions, which can be found on our application forms, questionnaires and certificates for each scheme.

General rules

- The client must only make claims consistent with the scope of certification,
- The client must not make any misleading or unauthorised comments regarding the certified product or the certification body.
- The client must upon suspension, withdrawal, or termination of certification discontinue the use of all advertising matter that contains any reference thereto and take action to return the certificate to Shirley®.

Use of the Notified Body Number

The Notified Body Number must only be used:

- In direct association with products or systems covered by the certification.
- by holder(s) of the certification.
- Use of Shirley® Notified Body Number does not extend to other companies which are:
  o part of the same corporate group as the Certificate holding company: or
  o named in a Certificate, for example as a supplier.
- Particular care must always be taken to avoid the association of the Shirley® Notified Body Number with
  other products or systems or schemes and with claims or information not contained in the Shirley® document.

Personal Protective Equipment Regulation

The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008, followed by the number of the notified body involved in production control monitoring (Module C2/D).

Construction Products Regulation

The EC mark consists of the letters 'CE', in the form given in Annex II of Regulation (EC) No 765/2008, followed by the last two figures of the year in which the mark was first affixed and the BTTG® notified body number.

Marine Equipment Directive

The EC mark consists of the Wheelmark, followed by the number of the notified body involved in Module D, E or F and the year, or the last two figures of the year, in which the mark was affixed.

12. Procedures for complaints and appeals

Complaints

A complaint is any formal expression of dissatisfaction raised with Shirley® in regard to its certification activities, its clients, or its services to clients.

All such complaints will be processed using the Shirley® procedure for complaints management. If the complaint is not in writing, confirmation will be requested. Complaints will be acknowledged in writing and investigated. The complainant will be advised of the outcome of the investigation. Complainants have the right of appeal, when a complaint is not resolved to the satisfaction of the complainant.

Shirley® will determine, together with the complainant and the certified client, whether and, if so to what , the subject of the complaint and its resolution is made public.

Appeals

An appeal is a formal review process when a client disagrees with a certification decision made by Shirley®, either to certify or not to certify.

Appeals must be received within 6 weeks of the complainant being advised of the outcome of the investigation into their complaint. If the appeal is not in writing, confirmation will be requested. One of the Shirley® Decision Makers will review the appeal. If it is rejected, the appellant will be informed of the reasons.

If the appeal is rejected, the complainant may seek a further appeal. An Appeals Panel will be appointed, including the Shirley® Managing Director and a representative from the Shirley® Certification Management Committee, which will review the appeal.

Representatives from Shirley®, technical experts, and the appellant will be invited to attend, as deemed necessary. The Appeals Panel will make a decision and set out any appropriate corrective action.

13. Requests for information

Shirley® will provide, upon request, information about:

- The geographical areas in which it operates;
- The status of a given certification;
- The name, standard, scope and geographical location (city and country) for a specific certified client.

Requests should be made to Shirley® using the contact details listed above.

14. Information provided to third parties

The Directives and Regulations for which Shirley® is appointed impose requirements on Notified Bodies for the provision of, or access to, information regarding their certification activities, and the results and conclusions of those activities.

Personal Protective Equipment Regulation

Any technical documentation and certification may be accessed by Ireland's competent authority, i.e. the Department of Enterprise, Trade and Employment.

Shirley® will inform the Department of any certificates or quality system approvals issued or extended, and any refusal, restriction, suspension or withdrawal of a certificate (Module B) or approval decision (Module C2 or D).

Shirley® will inform other notified bodies of any EU type-examination certificates and extensions or quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and will provide notified bodies carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative conformity assessment results.

On request, Shirley® will provide other notified bodies with information of EU type-examination certificates and extensions or quality system approvals which it has issued, and will provide notified bodies carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to relating to positive conformity assessment results.

On request, the European Commission, other PPE notified bodies and the other EU Member States may obtain a copy of EU type-examination certificates.
Following a reasoned request, Shirley® may provide the European Commission, other PPE notified bodies and the other EU Member States with a copy of the technical file and the reports of the examinations and tests conducted.

Construction Products Regulation

Shirley® will inform Ireland's competent authority, the Department of Housing, Local Government and Heritage, of any refusal, restriction, suspension or withdrawal of certificates.
Shirley® will inform the other CPR notified bodies with relevant information on issues relating to negative and, on request, positive results from assessments and/or verifications.

Marine Equipment Directive

All MED certification decisions and information, including details from the Declaration of Conformity, are uploaded to the MED database, held by the European Maritime Safety Agency (EMSA), located at:

https://portal.med.emsa.europa.eu/

- Marine Equipment with valid Module B and also valid Module D/E/F certification is visible to any public viewer who registers;
- Marine Equipment without a valid Module B and/or without valid Module D/E/F certification is only visible to the other MED Notified Bodies, the EU Member States, the European Commission and the European Maritime Safety Agency.

Shirley® will, on request, provide Ireland's competent authority, the Marine Survey Office, and the other MED Notified Bodies with the relevant information concerning the EC type-examination (Module B) certificates and additions issued and
withdrawn.

The other MED Notified Bodies may obtain a copy of the EC type-examination (Module B) certificate.

Shirley® will, on request, provide EU Member States and the other MED Notified Bodies with the relevant information concerning quality-system (Module D/E) approvals issued and withdrawn.