

機械類產品型式驗證實施及監督管理辦法(民國 103 年 11 月 28 日發布)

Regulations Governing the Implementation and Monitoring of Type Certification for

Mechanical Products (2014.11.28 Announced)

第一章 總則	
Chapter I General	
第 1 條	本辦法依職業安全衛生法（以下簡稱本法）第八條第五項規定訂定之。
Article 1	These Regulations are established in accordance with Paragraph 5, Article 8 of the Occupational Safety and Health Act (the Act).
第 2 條	<p>本辦法用詞，定義如下：</p> <p>一、機械類產品：指輸入或國內產製之機械、設備或器具產品，依本法第八條第一項規定，經中央主管機關公告應實施型式驗證者。</p> <p>二、產製：指生產、製造、加工或修改，包括將機械類產品由個別零組件予以組裝銷售，及於進入市場前，為銷售目的而修改。</p> <p>三、驗證實施程序：指技術性貿易障礙協定所稱符合性評鑑程序，包括直接或間接用以判定與技術性法規或安全標準是否相符之下列任何相關程序：</p> <p>(一) 取樣、試驗及檢查。</p> <p>(二) 評估、證明及符合性保證。</p> <p>(三) 登錄及認可。</p> <p>(四) 前三款之合併程序。</p> <p>四、驗證機構：指依本法第八條第一項規定，經中央主管機關認可辦理型式驗證之機構。</p>
Article 2	<p>The terms and vocabulary used in these Regulations shall be defined as follows:</p> <p>1. Mechanical products: machinery, equipment or appliances, imported or domestically manufactured, announced to be subject to type certification by the central competent authority in accordance with Paragraph 1, Article 8 of the Act.</p> <p>2. Produce: manufacture, make, process or modify, including the assembly of individual components to final mechanical products for sale, and modification of the products for purpose of sale before they are placed on the market.</p> <p>3. Certification procedures: conformity assessment procedures as mentioned in the Agreement on Technical Barriers to Trade, including any of the following procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.</p> <p>(1) procedures for sampling, testing and inspection;</p>

	<p>(2) procedures for evaluation, verification and assurance of conformity;</p> <p>(3) procedures for registration and approval;</p> <p>(4) combinations of the procedures mentioned in the preceding 3 subparagraphs.</p> <p>4. Certification body: bodies that are approved to perform type certification in accordance with Paragraph 1, Article 8 of the Act.</p>
第 3 條	<p>機械類產品（以下簡稱產品）之報驗義務人如下：</p> <p>一、產品在國內產製，為該產品之產製者。但產品委託他人產製，而以在國內有住所或營業所之委託者名義，於國內銷售時，為委託者。</p> <p>二、產品在國外產製，為該產品之輸入者。但產品委託他人輸入，而以在國內有住所或營業所之委託者名義，於國內銷售時，為委託者。</p> <p>三、產品之產製、輸入、委託產製或委託輸入者不明，或不能追查時，為銷售者。</p>
Article 3	<p>The obligatory applicant for mechanical products (hereinafter referred to as the products) shall be:</p> <p>1. the manufacturer, if the products are produced domestically. Where the products are contracted to others to produce and are placed on the market under the name of the contractor who has domiciles or business offices in Taiwan, the contractor shall be the obligatory applicant.</p> <p>2. the importer, if the products are produced in foreign countries. Where the products are contracted to others to import and are placed on the market under the name of the contractor who has domiciles or business offices in Taiwan, the contractor shall be the obligatory applicant.</p> <p>3. the seller of the products, if the manufacturer / importer / contractor of production or contractor of import is unknown and not able to be traced.</p>
第 4 條	<p>依本法第八條第一項規定應實施型式驗證之產品，未經驗證機構實施型式驗證合格，並取得型式驗證合格證明書（附表一）及張貼合格標章者，不得運出廠場或輸入。但依本法第八條第四項規定申請核准先行放行者，不在此限。</p>
Article 4	<p>Products that are subject to type certification in accordance with Paragraph 1, Article 8 of the Act shall not be shipped out of the production premises or imported if they are not type certified by the certification bodies, do not obtain the certificate of conformity to type certification (Appendix) and do not put up the certification</p>

	labels, except that an application for prior release is approved in accordance with Paragraph 4, Article 8 of the Act.
第 5 條	驗證之實施程序、項目及標準，中央主管機關得依國際經貿或勞工公約有關規定，並參酌相關國家標準、國際標準或其他技術性法規，另行公告之。
Article 5	The implementation procedures, items and standards for certification shall be stipulated and published by the central competent authority by following requirements of international trade or labor treaties and consulting relevant national standards, international standards or other technical regulations.
第 二 章 型 式 驗 證	
Chapter II Type Certification	
第 6 條	<p>報驗義務人申請產品型式驗證時，應填具申請書，並檢附載明下列事項書件，向驗證機構提出：</p> <p>一、符合性聲明書：製造者或輸入者簽署該產品符合型式驗證之實施程序及標準之聲明書。</p> <p>二、產品基本資料：</p> <p>(一) 型式名稱說明書：包括產品之型錄、名稱、外觀圖、商品分類號列、主機台及控制台基本規格等說明資訊。</p> <p>(二) 歸類為同一型式之理由說明書。</p> <p>(三) 主型式及系列型式清單。</p> <p>(四) 構造圖說，包括產品安全裝置之性能示意圖及安裝位置。</p> <p>(五) 有電氣、氣壓或液壓回路者，其各該相關回路圖。</p> <p>(六) 性能說明書。</p> <p>(七) 產品之安裝、操作、保養、維修說明書及危險對策。</p> <p>(八) 產品安全裝置及安全配備清單：包括相關裝置之品名、規格、安全性能與符合性說明、重要零組件驗證測試報告及相關強度計算。</p> <p>(九) 其他中央主管機關認有必要之技術文件資料。</p> <p>三、設立登記文件：工廠登記、公司登記、商業登記或其他相當於設立登記之證明文件影本。但依法無須設立登記或相關資料已於中央主管機關指定之資訊網站登錄有案，且其記載事項無變更者，不在此限。</p> <p>四、符合性評鑑證明文件：依型式驗證之實施程序及標準核發之符合性評鑑合格文件。但取得其他驗證證明文件報經中央主管機關同意者，得以該驗證證明文件替代符合性評鑑證明。</p> <p>前項申請書件未符規定者，驗證機構得通知報驗義務人限期補正，屆期未補正者，不予受理。</p> <p>驗證機構為辦理第一項文件資料之數位保存及管理，得要求報驗義務人提供相關資料之電子檔。</p> <p>報驗義務人提供之第一項所定文件為影本者，應註明與正本相符字樣並簽章，</p>

	<p>必要時，驗證機構得要求提出正本供查對。</p>
<p>Article 6</p>	<p>The obligatory applicant shall apply to certification bodies for type certification by completing an application form and providing the following documents:</p> <ol style="list-style-type: none"> 1. Declaration of Conformity: the declaration that the manufacturer or importer signs to declare conformity of the products to the implementation procedures and standards for type certification. 2. Basic information about the products: <ol style="list-style-type: none"> (1) description of the product type, including product catalog, product name, illustration of the appearance, product classification code (HS code or CCC code), specifications of the main processing unit and control unit, etc., (2) reasons for products being classified as the same type, (3) list of the main type and series of the type, (4) drawings of the construction, including illustration of the location of the product safety devices and their functions, (5) drawings of the electric, hydraulic or pneumatic circuit, if applicable, (6) instructions of performance, (7) instructions of the installation, operation, maintenance and repair of the product, as well as recommended practices for responding to hazards, (8) list of product safety devices and safety accessories, including the names, specifications, safety performance and compliance status, test reports of critical components and related strength calculations of the devices, and (9) other technical files required by the central competent authority. 3. Registration documents: factory registration, company registration, business registration or other equivalent documents that demonstrate official approval for establishment, except where registration is not required by laws or relevant information has been registered with no changes. 4. Conformity assessment certificates: conformity assessment certificates issued in accordance with the implementation procedures and standards for type certification. Where approval is obtained from the central competent authority, other certification documents may be used as alternatives to the

	<p>conformity assessment certificates.</p> <p>The certification body may notify the obligatory applicant to supply documents within a certain time limit if the application documents do not comply with the requirements. The application shall be denied if the documents are not supplied within the specified time limit.</p> <p>The certification body may request the obligatory applicant to provide electronic files for related documents mentioned in subparagraph 1 for purpose of digital storage and management.</p> <p>Where the documents mentioned in subparagraph 1 are provided in copies, the obligatory applicant shall note on the copies that they are identical to the originals and properly signed. The certification body may request that the originals of the documents be provided for check, if necessary.</p>
第 7 條	產品驗證合格證明文件經撤銷或產品不符安全標準而經廢止者，其原附符合性評鑑合格文件，不得再供申報符合性評鑑之用。
Article 7	Where a certificate of type certification is withdrawn, or rescinded due to noncompliance of products with safety standards, the conformity assessment documents used to apply for the certificate shall not be used again for purpose of reporting conformity assessment.
第 8 條	依雙邊或多邊相互承認協議，對方國核發之驗證合格證明文件，得視同第六條第四款之符合性評鑑證明文件。
Article 8	Certificates of product certification issued by countries that signed bilateral or multilateral mutual recognition agreements with the Republic of China shall be deemed as equivalent to the conformity assessment certificates mentioned in subparagraph 4, paragraph 1, Article 6.
第 9 條	報驗義務人檢附之技術文件資料，應以中文為主，並得輔以英文或其他外文。前項資料為外文者，除供工作者使用之安裝、操作、保養、維修及危險對策等，應有中文正體字譯本外，文件為英文以外之外文者，應附具英譯本對照。報驗義務人未依前二項規定辦理者，驗證機構得通知限期補正，屆期未補正或補正後仍不符規定者，不予受理。
Article 9	<p>The technical files provided by the obligatory applicant shall be written in Chinese and may be supplemented with information in English or other languages.</p> <p>Where the documents mentioned in the preceding paragraph are written in English, technical documents to be used by workers for installation, operation, maintenance, repair of the product or taking</p>

	<p>recommended practices for responding to hazards shall have translations in traditional Chinese. Documents that are written in foreign languages other than English shall have English translations for reference.</p> <p>The certification body may request that the obligatory applicant failing to comply with the preceding two paragraphs take corrective actions within a certain time limit. If corrective actions are not taken within the time limit, the application shall be denied.</p>
第 10 條	<p>驗證機構受理產品驗證申請時，應依中央主管機關指定之型式驗證實施程序及標準辦理。</p> <p>前項型式驗證實施程序，應包括產品設計及製造階段之符合性評鑑程序，並應依產品之型式及製造技術能力分別為之。</p>
Article 10	<p>The certification body shall follow the implementation procedures and standards for type certification for processing applications for product certification.</p> <p>The implementation procedures for type certification mentioned in the preceding paragraph shall include conformity assessment procedures at the design and production stages of the product, and shall be carried out based on types of products and production technologies.</p>
第 11 條	<p>驗證機構實施產品型式驗證，經審驗合格者，應發給附字號之型式驗證合格證明書。</p> <p>前項型式驗證合格證明書之有效期間，為三年。</p>
Article 11	<p>The certification body shall issue certificates of type certification with serial numbers when the application is reviewed to be in compliance.</p> <p>The term of validity of the certificate of type certification shall be in a period of 3 years.</p>
第 12 條	<p>型式驗證合格證明書有效期間屆滿前三個月內，除有第十八條及第二十條規定之情形外，報驗義務人得檢附展延申請書及相關書件向驗證機構申請展延三年。逾期申請展延者，應重新申請型式驗證。</p> <p>前項展延之申請，經驗證機構審查核可者，收繳舊證換發新證。</p>
Article 12	<p>The obligatory applicant may apply to the certification body for extension of the validity period by submitting an application for extension and related documents 3 months prior to the expiry date of the validity period. A new application for type certification shall be made if the application for extension is made after the expiry date.</p>

	Where the application for extension is approved by the certification body, the old certificate shall be collected before the new certificate is issued.
第 13 條	<p>驗證機構實施前條型式驗證之審驗，必要時，得要求生產廠場提供試驗用樣品，並就特定項目執行複測、抽樣、監督試驗或赴生產廠場實地就品管及製程查核。</p> <p>驗證機構執行前項監督試驗時，應報請中央主管機關同意，始得為之。</p>
Article 13	<p>The certification body may request that the production premise provide samples for testing, where necessary, for performing document review of type certification mentioned in the preceding Article. It may conduct testing of certain items, sampling, witnessed testing or visit the production premise to check the quality management and production processes.</p> <p>The certification body shall obtain approval from the central competent authority before conducting witnessed testing mentioned in the preceding paragraph.</p>
第 14 條	報驗義務人應保存型式驗證合格產品之符合性聲明書及技術文件，至該產品停產後至少十年。
Article 14	The obligatory applicant shall maintain declaration of conformity and technical files for products type certified for period of not less than 10 years after the products are no longer produced.
第 15 條	同一報驗義務人就同一型式之產品，不得重複申請型式驗證。但有第十二條第一項之情形者，不在此限。
Article 15	The same obligatory applicant shall not re-apply for type certification for the same type of products, unless there are situations specified in paragraph 1, Article 12.
第 16 條	<p>報驗義務人申請型式驗證，其產品之型式應依產品型號定之。但產品無型號者，得以規格、文字或編碼為之。</p> <p>前項產品之型號、規格、文字或編碼，應具有顯著識別性，並由報驗義務人於申請型式驗證時定之。</p> <p>基本設計相同之產品，得歸類為系列型式。</p>
Article 16	The type number of a product shall be used as the type for making the application for type certification. If the product has no type number, the specifications, characters or codes may be used as the type for type certification.

	<p>The type number, specifications, characters or codes of the product shall be easily identifiable and determined by the obligatory applicant when the application for type certification is made.</p> <p>Products with the same basic design may be classified as series of types.</p>
第 17 條	<p>經型式驗證合格之產品，報驗義務人應維持其與型式驗證合格證明書所載之名稱、型式、規格及功能特性相符，且實體不得與型式驗證合格證明書記載事項相異。</p> <p>有變更型式驗證合格證明書所載之名稱、型式、規格或功能特性者，應重新申請驗證。</p>
Article 17	<p>For type-certified products, the obligatory applicant shall maintain that they comply with the name, type, specifications and functions stated in the certificate of type certification, and the actual products shall not be different from those stated in the certificate of type certification.</p> <p>A new application for type certification shall be made if the name, type, specifications or functions stated in the certificate of type certification are to be changed.</p>
第 18 條	<p>已取得型式驗證合格之產品，於中央主管機關修正型式驗證實施標準時，其型式驗證合格證明書之名義人，應於規定期限內依修正後之標準，申請換發型式驗證合格證明書。</p>
Article 18	<p>For type-certified products, when the central competent authority revises standards for type certification, the holder of the certificate of type certification shall apply for re-issuance of the certificate against the revised standards within the specified time limit.</p>
第 19 條	<p>型式驗證合格產品之輸入者與型式驗證合格證明書之名義人非相同者，得經該證明書名義人之授權，向驗證機構申請核發授權放行通知書，辦理通關。</p> <p>前項授權放行通知書之授權範圍，及於證明書所列全部型號產品。</p> <p>第一項授權，經證明書名義人通知驗證機構終止者，驗證機構應廢止第一項同意授權放行通知書；其型式驗證合格經撤銷或廢止，或型式驗證合格證明書經註銷者，亦同。</p>
Article 19	<p>Where the importer of type-certified products is not the holder of the certificate of type certification, the importer may under the authorization of the certificate holder apply to the certification body for a prior-release notice for purpose of clearing the customs.</p> <p>The scope of authorization mentioned in the preceding paragraph shall be applicable to all types of products stated in the certificate.</p>

	<p>The certification body, upon receiving a notification from the certificate holder to terminate the authorization mentioned in paragraph 1, shall rescind the prior-release notice mentioned in paragraph 1 that it issued. The same shall be applicable to withdrawal or rescission of the compliance status of type certification as well as cancellation of the certificate of type certification.</p>
第 20 條	<p>報驗義務人對於取得型式驗證合格證明書之產品，有變更設計時，應依下列規定辦理：</p> <p>一、基本設計變更者，重新申請型式驗證。</p> <p>二、基本設計未變更而其系列產品變更者，申請系列型式驗證。</p> <p>三、前款變更不影響證明書登載事項及產品識別者，報請驗證機構備查。</p> <p>前項情形驗證機構認有必要時，得要求報驗義務人提出相關證明文件、技術文件或測試報告。</p>
Article 20	<p>The obligatory applicant shall observe the following requirements for changes made to the design of type-certified products:</p> <ol style="list-style-type: none"> 1. To make a new application for type certification when the basic design is changed, 2. To apply for series of type certification when the basic design is not changed yet changes are made to series of products, 3. To report to the certification body for record when the changes mentioned in the preceding subparagraph do not affect the information stated in the certificate and identification of the product. <p>The certification body may request the obligatory applicant to provide related documents, technical files or test reports, where necessary.</p>
第 21 條	<p>報驗義務人對於取得型式驗證合格證明書之產品，其生產廠場有增加、變更或遷移者，應報請驗證機構變更記載，並申請重新換發證明書。</p>
Article 21	<p>For type-certified products, the obligatory applicant shall report to the certification body for revisions to the information stated in the certificate of type certification concerning the additions, changes or relocation of production premises and make an application for a replacement certificate.</p>
第 22 條	<p>型式驗證合格證明書有遺失或毀損者，應申請補發或換發。</p> <p>因申請登載系列產品致其證明書原登載事項有變更者，報驗義務人應重新申請換發證明書，增列登載項目。</p>
Article 22	<p>Where the certificate of type certification is lost or damaged, an</p>

	<p>application for replacement or re-issuance of certificate shall be made.</p> <p>Where the content of certificate needs to be changed due to the application for adding series of types of the products, the obligatory applicant shall make a new application for re-issuance of certificate with the added information.</p>
<p>第 三 章 驗 證 機 構 之 認 可 及 管 理</p>	
<p>Chapter III Recognition and Management of Certification Bodies</p>	
<p>第 23 條</p>	<p>行政機關、學術機構或公益法人符合下列資格條件者，得向中央主管機關申請認可為驗證機構：</p> <p>一、具有從事型式驗證業務能力與公正性、固定辦公處所、組織健全且財務基礎良好。</p> <p>二、已建立符合國際標準 ISO/IEC 17065 或其他同等標準要求之產品驗證制度，並取得經中央主管機關認可之我國認證機構相關領域之認證資格。</p> <p>三、設有與型式驗證業務相關之專業檢測試驗室，並取得國際標準 ISO/IEC 17025 相關領域認證。</p> <p>四、擬驗證之各項產品均置有一名以上之專業專職之驗證人員。</p> <p>五、其他經中央主管機關公告之資格條件。</p>
<p>Article 23</p>	<p>Government agencies, academic institutes or non-profit legal persons possessing the following qualifications may apply to the central competent authority for becoming recognized certification bodies:</p> <p>1. To have the competence to perform certification activities and be impartial, have a fixed place for business, have a sound organization structure and have good financial infrastructure,</p> <p>2. To have established product certification systems in compliance with ISO/IEC 17065 or other equivalent standards, and to be accredited by the accreditation body in Taiwan recognized by the central competent authority in relevant fields,</p> <p>3. To have professional testing laboratories related to type certification and be accredited against ISO/IEC 17025 in relevant fields,</p> <p>4. To have one full-time professional certification personnel for each product category it intends to provide certification service, and</p> <p>5. Other qualifications stipulated by the central competent authority.</p>
<p>第 24 條</p>	<p>前條第五款之驗證人員，應具有下列資格之一：</p> <p>一、國內公立或立案之私立大學校院或教育部承認之國外大學校院機械或電機</p>

	<p>相關學系碩士以上，並具實際從事型式驗證相關產品之研究、設計、製造、安全檢查、安全測試或型式檢定實務經驗二年以上而有證明文件者。</p> <p>二、國內公立或立案之私立大專校院或經教育部承認之國外大專校院機械或電機相關科系畢業，並具實際從事型式驗證相關產品之研究、設計、製造、安全檢查、安全測試或型式檢定實務經驗五年以上而有證明文件者。</p> <p>三、國內公立或立案之私立高級工業職業學校或教育部承認之國外高級工業職業學校機械或電機相關科組畢業，並具實際從事型式驗證相關產品之研究、設計、製造、安全檢查、安全測試或型式檢定實務經驗七年以上而有證明文件者。</p> <p>四、其他受中央主管機關承認之資格者。</p>
Article 24	<p>The certification personnel shall possess one of the following qualifications:</p> <ol style="list-style-type: none"> 1. master degrees from mechanical or electrical engineering programs of graduate schools or higher of public or private universities in Taiwan or in other countries recognized by the Ministry of Education, and participation in certification-related research, design, production, safety inspection, safety testing, or having on-hand type verification experience, for 2 years or more with demonstration documents, 2. graduated from mechanical or electrical engineering departments of public or private universities or colleges in Taiwan or in other countries recognized by the Ministry of Education, and participation in certification-related research, design, production, safety inspection, safety testing, or having on-hand type verification experience, for 5 years or more with demonstration documents, 3. graduated from mechanical or electrical engineering departments of vocational high schools in Taiwan or in other countries recognized by the Ministry of Education, and participation in certification-related research, design, production, safety inspection, safety testing, or having on-hand type verification experience, for 7 years or more with demonstration documents, or 4. other qualifications recognized by the central competent authority.
第 25 條	<p>驗證人員應熟諳型式驗證之相關法規及技術規範，並由中央主管機關或其認可專業團體訓練合格登錄後，始得從事型式驗證業務。</p>
Article 25	<p>The certification personnel shall be familiar with technical regulations and technical specifications related to type</p>

	certification and shall be registered after having taken training courses given by the central competent authority or professional groups recognized by the central competent authority before they can conduct type certification activities.
第 26 條	經依前條登錄之驗證人員，不得兼任型式驗證之檢驗工作。
Article 26	The registered certification personnel mentioned in the preceding Article shall not conduct inspection involved in the process of type certification.
第 27 條	<p>具有第二十三條資格條件之機構(以下簡稱申請人)申請認可為驗證機構時，應填具申請書，並檢附下列文件：</p> <p>一、註明擬申請之產品驗證項目之文件。</p> <p>二、符合第二十三條資格條件之證書影本及相關佐證文件。</p> <p>三、驗證人員名冊及其擬任之產品驗證項目。</p> <p>四、組織架構圖及業務功能說明表。</p> <p>五、機構之辦公與工作區佈置圖及地理位置簡圖。</p> <p>六、品質手冊、品質文件系統架構及一覽表。</p> <p>七、其他經中央主管機關認有必要之文件。</p> <p>前項申請文件不完備者，中央主管機關得通知限期補正；屆期不補正或補正後仍不符規定者，不予受理。</p>
Article 27	<p>The organization meeting the qualification requirements specified in Article 23 (hereinafter referred to as the applicant) shall complete an application form and submit the following documents when they apply for becoming a recognized certification body:</p> <ol style="list-style-type: none"> 1. Documents stating the scope of product certification, 2. Copies of demonstration documents of qualifications in compliance with Article 23 and related supporting documents, 3. List of certification personnel and the product certification activities they are in charge of, 4. Explanations about the organizational chart and functions, 5. Layout of the offices and working areas as well as a simple graphic of geographical locations, 6. Quality manuals, structure and list of quality documents, and 7. Other documents that are deemed necessary by the central competent authority. <p>The central competent authority may notify the applicant to supply documents within a certain time limit if the application documents do not comply with the requirements. The application shall be denied if the documents are not supplied within the specified time limit.</p>

<p>第 28 條</p>	<p>申請人檢具申請文件符合前條規定者，中央主管機關得邀請學者專家組成評鑑小組，進行實地評核。</p> <p>前項實地評核應就下列事項為之，並提出評核報告：</p> <ol style="list-style-type: none"> 一、產品驗證制度符合國際標準 ISO/IEC 17065 或其他同等標準規範之要求。 二、具有產品型式驗證業務所需技術性法規、實施程序、安全標準、國家標準或國際標準規定之執行能力。 三、具有執行產品型式驗證業務所需國家標準、國際標準或其他相關標準所定之風險管理能力。 四、具有對驗證人員之任免、培訓、認可、監督、考核及管理所需之相關內部規範文件及執行能力。 五、具有推動產品型式驗證業務之內外部符合性評鑑機構之資格認可、監督、考核、維護及管理所需之相關內部規範文件及執行能力。 六、具有擬訂驗證產品之監督計畫及執行能力。 七、其他經中央主管機關認有必要事項。 <p>實地評核未符規定者，中央主管機關應將不符事項通知申請人限期改善。屆期未完成改善者，不予認可。</p>
<p>Article 28</p>	<p>The central competent authority may establish an assessment team comprised of academic scholars and experts to conduct on-site assessment if the application documents provided by the applicant comply with the requirements mentioned in the preceding Article.</p> <p>The on-site assessment mentioned in the preceding paragraph shall cover the following items and an assessment report shall be provided:</p> <ol style="list-style-type: none"> 1. Compliance of the product certification systems with ISO/IEC 17065 or other equivalent standards, 2. Ability to implement technical regulations, operation procedures, safety standards, national standards or international standards, required by type certification activities for the products, 3. Ability to manage risks specified in national standards, international standards or other relevant standards, in order to implement type certification activities for the products, 4. Availability of internal documents required for the employment, training, recognition, surveillance, assessment and management of certification personnel and the ability to implement the documents, 5. Availability of internal documents for the recognition of qualifications, surveillance, assessment, maintenance and management of internal and external conformity assessment bodies, in order to promote type certification activities for the

	<p>products, and the ability to implement the documents,</p> <p>6. Ability to prepare monitoring plans for certified products and to implement the plans, and</p> <p>7. Other information required by the central competent authority.</p> <p>The central competent authority shall notify the applicant of nonconformities found during the on-site assessment and request that corrective actions be taken within a certain time limit. The application shall be denied if corrective actions are not taken within the specified time limit.</p>
第 29 條	<p>前條實地評核認可後，中央主管機關應核發認可文件，公告認可辦理產品型式驗證業務。</p> <p>驗證機構辦理產品型式驗證業務時，應以驗證機構名義為之。但與型式驗證相關之符合性評鑑工作，得由驗證機構依其專業及技術需求，另委由報經中央主管機關核准之符合性評鑑機構辦理。</p> <p>前項符合性評鑑工作，因情況特殊，擬採監督試驗或臨場試驗者，驗證機構應擬具評估分析報告，報經中央主管機關核准後始得為之。</p>
Article 29	<p>The central competent authority shall issue an approval document and publish the recognition status of the applicant to perform type certification activities of products, if the on-site assessment mentioned in the preceding Article yields approval of the application.</p> <p>The certification body shall conduct type certification activities in its name. Nevertheless, conformity assessment activities related to type certification may be subcontracted to conformity assessment bodies approved by the central competent authority based on its professional and technological needs.</p> <p>Where the certification body intends to have the conformity assessment activities mentioned in the preceding paragraph be done in the manner of witnessed testing or on-site testing, it shall prepare related evaluation and analysis reports and obtain approval from the central competent authority.</p>
第 30 條	<p>中央主管機關對驗證機構之認可期限為三年，期限屆滿前六十日內，驗證機構得申請展延。</p> <p>中央主管機關核准前項展延時，準用第二十九條第一項之公告認可規定。</p>
Article 30	<p>The term of validity of the recognition granted to certification bodies shall be in a period of 3 years. Applications for extension of the validity period may be made by the certification body 60 days prior to the expiry date.</p>

	Where the central competent authority approves the application for extension mentioned in the preceding paragraph, the requirements stipulated in Paragraph 1, Article 29 regarding the publication of recognition status shall apply mutandis mutatis.
第 31 條	驗證機構辦理產品型式驗證及相關符合性評鑑工作，非有正當理由，不得拒絕受理或為差別待遇。
Article 31	The certification body performing type certification and related conformity assessment activities shall not deny or discriminate applications without justified reasons.
第 32 條	驗證機構應將各該型式驗證之相關資料、執行情形及結果之電子檔，傳送至中央主管機關指定之資訊申報網站備查。
Article 32	The certification body shall transmit electronic files of related documents concerning type certification, implementation status and results to Information Reporting Website designated by the central competent authority for record.
第 33 條	驗證機構擬增列驗證類別或項目者，應檢具申請書及相關資料向中央主管機關申請核准，並重新核發認可文件。 認證範圍經我國認證機構減列時，驗證機構應即停止辦理型式驗證範圍內受影響之符合性評鑑業務，並於三個月內檢具申請書向中央主管機關申請變更業務範圍及重新核發認可文件。
Article 33	The certification body shall apply to the central competent authority for approval if it intends to extend certification scope or items by submitting an application form and related documents. A new approval of recognition shall be issued. Where the accreditation scope of the certification body is reduced by the accreditation body in Taiwan, the certification body shall stop performing conformity assessment activities in relevant type certification fields affected by the reduction of accreditation scope. An application for changes to the type certification scope shall be made to the central competent authority for issuing a new approval of recognition.
第 34 條	驗證機構遷移地址或變更其他基本資料者，應檢附相關文件向中央主管機關申請變更記載；未經審查核准前，不得執行型式驗證。
Article 34	The certification body shall apply to the central competent authority by submitting related documents for changes to the content of approval documents within 3 months after it relocates to a new address or modifies its basic information. Type certification activities shall not be conducted before approval of the changes is

	granted.
第 35 條	驗證機構之驗證人員有出缺、增補或任免之異動者，應於異動發生之日起十五日內，檢附異動人員資料報請中央主管機關備查。
Article 35	The certification body shall report to the central competent authority for record within 15 days when there are changes to the certification personnel as a result of resignation, recruitment or employment.
第 36 條	驗證人員出缺未補實，致不符合第二十三條第五款規定者，中央主管機關得令該驗證機構暫停辦理有關型式驗證工作。 前項情形驗證機構應於驗證人員補實後，檢附驗證人員基本資料，報請中央主管機關准予恢復辦理型式驗證工作。
Article 36	The central competent authority may order the certification body to stop conducting type certification activities when there are vacancies of certification personnel leading to non-conformities to subparagraph 5 of Article 23. The certification body shall apply to the central competent authority for resuming the conduction of type certification by submitting the basic information of the certification personnel after the vacancies mentioned in the preceding paragraph are filled.
第 37 條	驗證機構未經中央主管機關核准展延認可期限者，於原認可期限屆滿前三十日內，不得受理驗證案件。
Article 37	The certification body shall not accept applications for type certification 30 days prior to the expiry date if it does not obtain approval from the central competent authority for extending the term of validity.
第 38 條	中央主管機關應對驗證機構每年辦理業務定期查核及不定期督導；驗證機構無正當理由者，不得規避、妨礙或拒絕。
Article 38	The central competent authority shall perform regular checks and irregular monitoring to certification bodies each year and the certification body shall not evade, impede or refuse the checks or monitoring without justified reasons.
第 39 條	驗證機構有下列情形之一者，中央主管機關得令其暫停辦理型式驗證，並限期改善： 一、經國內認證機構暫停其認證資格。 二、驗證機構所採用之符合性評鑑機構，未有中央主管機關核准。 三、經通知限期提供資料，無正當理由屆期未提供。 四、中央主管機關辦理查核，無正當理由未配合辦理。 五、有申訴、陳情或爭議案件時，應配合辦理而未配合。

	前項情形經改善，並經中央主管機關認定符合者，始予恢復辦理型式驗證。
Article 39	<p>Under any of the following circumstances, the central competent authority may order the certification body to stop performing type certification activities and request that correction actions be taken within a certain time limit:</p> <ol style="list-style-type: none"> 1. where its accreditation status is suspended by the accreditation body in Taiwan, 2. where the approval is granted by the central competent authority for conformity assessment bodies it subcontracted, 3. where the documents are not provided without justified reasons within the specified time limit, 4. where it refuses to be checked by the central competent authority without justified reasons, or 5. where it does not assist in processing appeals, complaints or disputes that it has the obligation to provide assistance. <p>Conduction of type certification shall be resumed only after the situations mentioned in the preceding paragraph are improved and confirmed by the central competent authority to be in compliance with related requirements.</p>
第 40 條	<p>驗證機構有下列情形之一者，中央主管機關得撤銷或廢止其認可：</p> <ol style="list-style-type: none"> 一、主動申請終止認可。 二、經國內認證機構撤銷或廢止其認證資格。 三、驗證機構採用之符合性評鑑機構，皆經中央主管機關撤銷或廢止核准。 四、驗證機構喪失執行型式驗證業務能力，或有礙公正有效執行型式驗證業務。 五、違反利益迴避或保密義務原則。 六、逾越授權範圍或怠於辦理型式驗證及相關符合性評鑑業務。 七、違反第三十一條規定。 八、未依第三十三條規定辦理申請核准或變更，或未經核准前，擅自執行型式驗證業務。 九、違反第三十八條規定。 十、未於第三十九條規定期間內完成改善，並經中央主管機關認定符合者，逕自恢復型式驗證業務。 十一、核發之驗證合格證明書有虛偽不實之情事。 十二、未依規定繳納規費，經通知限期繳納，屆期仍未繳納。 十三、接受利害關係者餽贈財物、飲宴應酬或請託關說，或假借職務上之權力、方法、機會圖本人或第三人不正利益，情節重大。 十四、其他違反法令規定，情節重大。

Article 40	<p>Under any of the following circumstances, the central competent authority shall withdraw or rescind the approval granted to the certification body:</p> <ol style="list-style-type: none"> 1. where the certification body applies for terminating the approval, 2. where the accreditation of the certification body is withdrawn or rescinded by the accreditation body in Taiwan, 3. where the approval of subcontracted conformity assessment bodies was withdrawn or rescinded by the central competent authority, 4. where the certification body loses the ability to perform type certification activities or is unable to maintain impartiality to perform type certification activities effectively, 5. where the principles of avoidance of conflict of interest or observance of confidentiality are violated, 6. where the certification body performs type certification or conformity assessment activities beyond the scope it is authorized or in a manner of tardiness, 7. where the provisions of Article 31 are violated, 8. where the application for approval or for changes is not made in accordance with Article 33 or conduction of type certification is resumed before the approval is obtained, 9. where the provisions of Article 38 are violated, 10. where corrective actions are not taken within the specified time limit in accordance with Article 39 and conduction of type verification activities is resumed before the central competent authority confirms compliance of the corrective actions, 11. where fraudulence is found for the issuance of certificate of type certification, 12. where the fees are not paid and still not paid within the notified time limit, 13. where the certification body accepts gratuities such as monetary or material gifts, meals or other entertainment, or of instances of entreaties or lobbying from interested parties, or take advantage of their powers, procedures or opportunities to seek illegitimate gain for itself or third parties and the violations are significant, or 14. where the violations against other laws and regulations are significant.
第 41 條	有第三十七條及前條情形時，驗證機構應將未完成之驗證案件交由中央主管機

	<p>關指定之其他驗證機構辦理。</p> <p>驗證機構之認可經撤銷或廢止者，自認可終止日起三年內，不得重新申請認可為驗證機構。但依前條第一款主動申請終止認可者，不在此限。</p>
Article 41	<p>For circumstances mentioned in Article 37 and the preceding Article, the certification body shall forward cases not completed to other certification bodies designated by the central competent authority. The certification body of which the approval of recognition is withdrawn or rescinded shall not apply for becoming a recognized certification body within 3 years from the date the approval is terminated, except where recognition is terminated as a result of application made by the certification body in accordance with subparagraph 1 of the preceding Article.</p>
第 42 條	<p>驗證機構應於認可終止後七日內，將所有型式驗證相關符合性評鑑業務案件之完整資料移交中央主管機關指定之機構。</p>
Article 42	<p>The certification body shall deliver the complete files of all conformity assessment cases related to type certification to organizations designated by the central competent authority within 7 days before the expiry date of recognition.</p>
<p>第 四 章 監 督 及 管 理</p>	
<p>Chapter IV Supplementary Provisions</p>	
第 43 條	<p>中央主管機關對於驗證機構之能力評鑑、技術一致性確認、人力培訓與資格審定及登錄管理等，依本法第五十二條規定，得委託國內專業團體辦理之。</p>
Article 43	<p>The central competent authority may, in accordance with Article 52 of these Regulations, subcontract domestic professional groups to conduct assessments of competence, confirmation of technological consistency, training of human resources and review of qualifications, management of registration, etc. of the certification bodies.</p>
第 44 條	<p>報驗義務人有下列情事之一者，中央主管機關應註銷其型式驗證合格證明書：</p> <p>一、自行申請註銷。</p> <p>二、設立登記文件經依法撤銷、廢止或註銷。</p> <p>三、事業體經依法解散、歇業或撤回認許。</p> <p>四、經中央主管機關查核發現有不合規定情事。</p>
Article 44	<p>Under any of the following circumstances, the central competent authority shall cancel the certificate of type certification issued to the obligatory applicant:</p> <p>1. where cancellation of the certificate is made upon application by the obligatory applicant,</p>

	<p>2. where the registration document of establishment is withdrawn , rescinded or cancelled in accordance with related laws,</p> <p>3. where the business entity is dismissed or shut down or its approval is withdrawn, or</p> <p>4. where non-conformities are found by the central competent authority during checks.</p>
第 45 條	<p>以詐欺或虛偽不實之方法取得型式驗證合格者，應撤銷其資格，並限期繳回證明書；其有涉及刑責者，另移送司法機關依法處理。</p> <p>構造規格特殊之機械類產品有前項情事，經中央主管機關撤銷核准其採用適當檢驗方式者，型式驗證合格標章亦應一併撤銷，並由驗證機構通知限期繳回型式驗證合格證明書。</p>
Article 45	<p>Where the certificate of type certification is obtained by fraudulent or deceptive means, the central competent authority shall withdraw related qualifications of the obligatory applicant and shall request the certificate be returned within a certain time limit. Where criminal charges are involved, the cases shall be forwarded to judicial organizations for processing.</p> <p>For the situation mentioned in the preceding paragraph occurs to mechanical products with special structures, where the central competent authority withdraws the approval for using appropriate inspection methods, the type certification label shall be withdrawn accordingly and the certification body shall request that the certificate of type certification be returned within a certain time limit.</p>
第 46 條	<p>報驗義務人有下列情事之一者，中央主管機關應廢止型式驗證合格證明書：</p> <ol style="list-style-type: none"> 一、經購樣、取樣檢驗結果不符合型式驗證實施標準。 二、經限期提供型式驗證合格證明書、技術文件或樣品，無正當理由拒絕提供或屆期仍未提供。 三、驗證合格產品因瑕疵造成重大傷害或危害。 四、產品未符合標示規定，經通知限期改正，屆期未改正。 五、未依第十四條規定期限保存經型式驗證之產品符合性聲明書及技術文件。 六、違反第十七條規定，產品與型式驗證合格證明書所載不符，經通知限期改正，屆期未改正完成。 七、經依第十八條規定，限期依修正後驗證標準換發型式驗證合格證明書，屆期未完成。 八、驗證合格產品生產廠場不符合製造階段之符合性評鑑程序。 九、未繳納驗證規費，經通知限期繳納，屆期未繳納。 十、產品經公告廢止實施型式驗證。

	<p>十一、其他經中央主管機關認定違規情節重大者。</p>
<p>Article 46</p>	<p>Under any of the following circumstances involving the obligatory applicant, the central competent authority shall rescind the certificate of type certification:</p> <ol style="list-style-type: none"> 1. where the inspection results of purchased products or sampled products do not comply with the standards of type certification, 2. where the certificate of type certification, technical files or samples are not provided within the notified time limit or are not intended to be provided without justified reasons, 3. where the certified product causes significant hurt or damages due to defects, 4. where the products do not comply with labeling requirements and corrective actions are not taken within the notified time limit, 5. where the declaration of conformity and technical files of type-certified products are not maintained for the specified time period in accordance with the provisions of Article 14, 6. where the provisions of Article 17 are violated because the products are different from those stated in the certificate of type certification and corrective actions are not completed within the notified time limit, 7. where the re-issuance of certificate of type certification against revised certification standards is not completed within the specified time limit in accordance with Article 18, 8. where the production premises of certified products do not comply with the conformity assessment procedures at the production stage, 9. where the certification fees are not paid within the notified time limit, 10. where type certification is no longer required for the product item, or 11. where the violations are considered significant by the central competent authority.
<p>第 47 條</p>	<p>我國與他國、區域組織或國際組織簽定雙邊或多邊相互承認協定或協約者，中央主管機關得依該協定或協約所負義務，承認依該協定或協約規定所簽發之試驗報告、檢驗證明及其他相關驗證證明。</p> <p>對於國外輸入之產品，其報驗義務人所附經中央主管機關依前項規定承認之國外試驗報告、檢驗證明及其他相關驗證證明，驗證機構得承認其效力，並據以免除第四條所定全部或部分之驗證或測試。但因未簽定協定、協約或其他特殊</p>

	原因致執行有困難者，驗證機構得報經中央主管機關核准，以實驗室對實驗室方式相互承認試驗報告。
Article 47	<p>Where bilateral or multilateral mutual recognition agreements or conventions are signed between the Republic of China with other countries, regional organizations or international organizations, the central competent authority may recognize test reports, inspection certificates or other related certification documents in accordance with the obligations specified in such agreements or conventions.</p> <p>For imported products, the certification body may recognize the foreign test reports, inspection certificates and other related certification documents provided by the obligatory applicant and recognized by the central competent authority in accordance with the provisions of the preceding paragraph. The whole or part of the certification or testing stipulated in Article 4 can therefore be waived. The certification body may apply to the central competent authority for approval on the acceptance of test reports via the arrangement of mutual recognition between testing laboratories if such agreements or conventions do not exist, or there are difficulties in accepting such certificates due to special reasons.</p>
第 48 條	本辦法所定各種書表格式，由中央主管機關定之。
Article 48	The forms of documents mentioned in these Regulations shall be prescribed by the central competent authority.
第 五 章 附 則	
Chapter V Others	
第 49 條	本辦法自中華民國一百零四年一月一日施行。
Article 49	These Regulations shall take effect on January 1, 2015.

(驗證機構名稱)


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型式驗證合格證明書

Certificate of Conformity to the Type-Certification scheme
Of the regulated machinery, equipment and tools

證明書字號：

Certificate No.

茲據_____申請型式驗證，經審驗結果符合安全標準，准予使用合格標章  及識別號碼：_____。其登載事項如下：

The application made under the Type-Certification scheme has been reviewed and found to be in compliance with related safety standards.

Therefore, the following product is granted with the Conformity Mark  and the Identification No. _____. Details of the certificate are as follows:

名義人：

Holder

統一編號：

Uniform No.

地址：

Address

生產廠場：

Factory

廠址：

Factory address

產品種類名稱

Type/ name of product

貨品分類號列：

C.C.C. Code

中文名稱：

Chinese name

英文名稱：

English name

型式：

Type

系列型式：

Series of the type

依據標準：

Specified standards

驗證機構核發戳記

(本證書經勞動部認可之機構用印後生效)

This certificate is issued by the certification body designated by MOL.

(This certificate will become effective only when stamped with the seal of the certification body designated by the Ministry of Labor.)

本證明書有效期限自_____年____月____日至_____年____月____日

Valid period from _____ (year) (month) (day) to _____ (year) (month) (day)

發證日期：中華民國_____年____月____日

Date of issue _____ (year) (month) (day)

註1：持本證明書輸入型式驗證產品時，輸入者須與本證明書之名義人相同。

(驗證機構名稱)

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型式驗證合格證明書(附頁)

Attachment for Certificate of Conformity to the Type-Certification scheme
Of the regulated machinery, equipment and tools

證明書字號：

Certificate No.

產品名稱 name of product	型式 Type	規格 Specification	功能特性 Character	備註 Remark