1. 目的 Purpose

為使獲取本機構管理系統證書的組織瞭解相關驗證規則事項，特制定本文件。This document is for the certified organization to understand related certificate rules

2.適用範圍 Scope

適用於已經正式獲取本機構頒發的管理系統驗證證書的客戶（也適用擬申請管理系統驗證的客戶作為驗證規則的預先瞭解）。This document is applicable to the certified organization. (it is also for the applicant to understand certificate rule in advance)

3. 規則事項概述 Provision description

3.1 本公司全體成員感謝你們選擇了我們作為合作的夥伴，並對貴組織的管理系統獲得驗證註冊表示衷心的祝賀。我們熱烈歡迎貴組織加入本公司的信譽共同體，在證書有效期內，本公司與貴組織將榮辱與共，協同完成獲證管理系統的維護、改進工作，繼續深化管理系統管理，以期取得更佳的經濟效益及社會效益。 All our staff appreciate you for choosing our company as your partner. Congratulate to you for your management system has been certified and registered . ARES appreciate your respected organization shall be our partner of credit community. In order to obtain better economic and social benefits, we will support your management system for maintain, improve, and further study during your certificate valid period.

3.2 本公司對獲證管理系統維護管理的歸屬部門為驗證部，負責組織協調本公司與獲證組織間的日常聯絡、追查稽核等工作，本公司管理部協助其工作。同時本公司將試行在與獲證組織協商後，與客戶相關人員的定期訪問形式，保持日常聯絡的經常化。另外，本公司負責對來自獲證組織、有關政府職能部門、社會團體和個人的重大申訴和抱怨的處理。Our audit department shall take charge in the certified organization. Shall keep daily contact with client, remind certified organization for surveillance audit. Management department shall support audit department. Our company purpose a trial for paying regularly visit to our client, keep in frequent touch with client. We also handle major complain from relevant governmental function and social community.

3.3 對管理系統獲證的維護管理須符合有關的認證規範及作為信譽共同體的一致性要求，為此

本公司與貴組織必須協同，以便在對獲證管理系統的維護過程中，在所涉及的以下各方面工作上都能保持良好的運作。 In order to carry out all work smoothly, as requirement of a credit community, manage certified organization must conform to relevant certificate provision, our company must work together with your organization.

3.4 關於驗證證書、驗證資格、證書、標誌的使用規則：具體執行 ARES-WI-20《驗證證書及驗證標誌使用規則》的有關規定。The use rule for certificate, qualification and logo must conform to ARES-WI-20《certification certificate and certification mark usage rules》provision.

3.5 對獲證組織追查稽核 Surveillance audit to certified organization

追查稽核是本公司驗證獲證組織的管理系統是否持續運作，同時考慮獲證組織運作方面的變化是否對其系統產生了不利的影響，並評定其系統是否滿足驗證要求。 Surveillance audit shall check whether the certified organization continue implement their management system, whether any major changes about implementation have bad effect on management system , and assess whether the management system still meet the assessment requirement.

3.5.1 追查稽核分定期和不定期兩種形式 There are two forms of surveillance audit: random and fixed period.

i) 本公司對獲證組織定期的追查稽核在證書的有效期內每年一次非均衡分佈進行，正常情況下初次驗證之後第一次追查稽核的日期，自驗證決定當日起不應超過 12 個月。本公司驗證部將提前三個月通知各獲證組織本年度追查稽核的具體日期時間安排。 Our company shall implement fixed period surveillance audit every year. Normally, the next surveillance audit date should within 12monthes after the certification decision. Our audit department shall inform certified organization the detail next surveillance audit agenda information.

ii) 不定期追查稽核由本公司安排，通常是在獲證組織管理系統的有效性可能出現失控情況時進行。以下情況，可進行不定期的追查稽核： Our company perform random surveillance audit to the certified organization when their management system maybe out of control. Our company perform random surveillance audit when following situations arose:

a.相關方對獲證組織有嚴重抱怨，或反應其有隱瞞事實真相； Serious complain from relevant party, or relevant party accuse the certified organization intend to hide the truth.

b.獲證組織的產品被相關機構抽查不合格；The product of the certified organization has

been sampling checked as non-conformity.

c.管理系統有較大變化、影響到系統運行的有效性；Major change in management system has effect on the effectiveness of the implementation of the management system.

d.正常追查稽核時有較多不合格，稽核組建議增加追查稽核。If there are several NC，audit team will advise to increase follow-up audit

3.5.2 追查稽核的實施 Conducting the surveillance audit

追查稽核由本公司組織實施，具體的追查稽核活動將由本公司根據年度計畫安排，以派出合格的稽核組進行現場稽核的方式進行。定期追查稽核的現場稽核計畫由稽核組長於稽核實施前一周通知，以便獲證組織做出安排。非定期追查稽核計畫可於稽核組到現場後提交獲證組織，也可提前預知。非定期追查稽核不收取稽核費用。Surveillance audit shall be conducted by our company, the detail activities shall be arranged by our company according to the annual plan. We shall arrange qualified audit group to conduct on-site audits. Audit team leader shall notice the certified organization and send them the site audit plan one week in advance, for the convenience arrangement of certified organization. Random surveillance audit plan shall be provided when audit team arrive or in advance. Random surveillance audit will be free charge.

3.5.3 追查稽核的延期 Delay for surveillance audit.

確因特殊原因，獲證組織無法按時接受定期追查稽核，應書面向本公司提出延期申請，獲批准後可延期。因延期追查稽核有可能引至該獲證客戶管理系統驗證證書的暫時終止或終止。Due to specific reason, certified organization couldn’t accept surveillance audit, should submit written application to our company, after get approval, the surveillance audit can be delayed. As delay for surveillance audit, it may cause the suspension or termination for the management system certificate.

3.6 獲證組織通報制度的規則 Report system rules for certified organization

3.6.1 通報制度的是本公司與獲證組織間進行溝通的一種手段，該制度要求獲證組織指定一個常設機構負責管理系統的維護並保持與本公司的經常性聯絡，及時反應有關資訊。當獲證組織發生如下情況時，應在一周內及時以書面形式向本公司通報： Report system is a way of company keep touch with certified organization. The system requires certified organization appoint a specific department to maintain the implementation of the management

system and keep daily touch with our company. The certified organization should feedback information to our company timely, When follow status occur, certificated organization should submit written notice to our company.

a.管理手冊等管理系統文件作重大修改；Major change in management document such as management manual.

b.管理系統覆蓋的產品結構、生產規模、場地發生重大變化；Major change in product structure, production scale or site which covered by management system.

c.組織負責人，尤其是最高管理者發生變動，或組織機構發生了較大的變動；Major change in the head of the organization, especially top management or major change of organization structure.

d.發生了重大的品質、環境污染物超標排放、職業安全衛生事故、食品安全、資訊安全等事故；When quality, environment, occupational health and safety accident, excess emissions of pollutants, food safety accidents, information security accidents occur.

e.國家主管部門的產品或環境檢查抽查不合格；When quality or environment sampling checked by governmental function parties as non-conformity.

f.產品出現較大批量的不合格或因品質問題引起了用戶退貨，且退貨量較大；Large quantity non-conformance products occur or large quantity products returned from customer side due to serious quality issue.

g.用戶有重大抱怨並產生了較大影響的；Serious complain from user side and has great influence.

h.其他涉及驗證範圍的改變； Change in other relevant certification scope.

i.聯繫方式發生變化時。Contact window changed.

3.6.2 凡與管理系統有關的較大變化，影響到管理系統運行及其有效性的，都應在通報的範圍之內。All major change related to management system, have influence on the effective implementation of management system.

3.6.3 書面報告的內容包括情況說明、原因，已採取或擬採取的措施等，事後須向本公司報告矯正結果的情況。 Written report content includes: status description, reason, actions have taken or will take; the certified organization shall report the corrective result to our company.

3.7 申訴和抱怨的處理規則： 執行 ARES-QP-04《申訴和抱怨處理程序》的有關規定。 Handle

rules for appeals and complains: follow ARES-QP-04《appeals and complains procedure》

3.8 增列或減列驗證範圍及組織名稱、地址的變更 Expanding or reducing certification scope, change for organization name or address

3.8.1 增列驗證範圍的情況 Status for expanding certification scope

a.如管理系統依據的模式標準變化；Management system standard change

b.增加管理系統覆蓋的產品；Expand the certification scope

c.管理系統覆蓋的運作場所增大。Operation place which covered by management expanded .

3.8.2 減列驗證範圍的情況 Status for reducing certification scope

a.如管理系統依據的模式變化；Management system standard change

b.減少管理系統覆蓋的產品或原產品中部分停產或改產；Reduce product certification scope or prior products EOL or changed

c.管理系統覆蓋產品的運作場所縮小 Operation place which covered by management reduced.

3.8.3 申請方式：獲證組織要求增列或減列驗證範圍時，應在下次追查稽核或重新驗證前的一個月內提出書面申請，填寫申請表、簽訂驗證合約，原則上，不臨時接受增列範圍的申請；Application means: when certificated organizations require expands or reduces the certification scope, should submit written application within one month prior to the surveillance audit. Fill application form, sign contract. We don't accept temporary application for expanding certification scope in principle.

a.要求增列或減列驗證範圍的有關產品的說明書； Detail product specification description which required be expanded or reduced.

b.申請增列的產品的研製或生產全過程能力（包括技術要求、作業流程、關鍵／特殊工序、新添重要設施，人員培訓等）的說明；Detail description of the design and produce ability which required be expanded.(include technical requirement, operate procedure, critical/special process, new infrastructure and staff training)

c.申請減列驗證範圍的理由和改產／停產說明；Apply reducing the scope reasons and suspending explanation

d.手冊、程序相應增刪部分。Changes in management system manual or procedure

3.8.4 稽核 Audit

3.8.4.1 稽核組按照有關驗證稽核的程序實施稽核並完成有關規定的記錄，尤其對增列驗證範圍的過程、產品及其所涉及的文件制度、人員能力等進行重點檢查與取證。Audit team conduct audit activity according to relevant procedure document and complete relevant required record. Especially focus on sampling check for expanding scope product, process, file system and staff ability .

3.8.4.2 當獲證組織的增列驗證範圍的產品、過程取證無具體事實的，公司不予認同其增列該驗證範圍。When certified organization can't provide actual expanding product or process, company will not accept the expanding scope.

3.9 重新驗證稽核的申請 Application for recertification

證書有效期屆滿或者恢復使用已暫停的證書，組織如要繼續保持對其管理系統的驗證，可向本公司提出重新驗證稽核申請，重新驗證稽核一般應在證書有效期到期 1 個月內向本公司提交 ARES-FM-01《驗證申請表》並簽訂重新驗證合約，重新驗證後重新頒發驗證證書，進入下一個證書有效期。 When the certificate is out of date, or restore suspending certificate, the certified organization would like continuously keep the certificate, he/she could apply for recertification audit. He/she should submit ARES-FM-01《certification application form》and sign contract with our company within one month prior to the expiration date. After the recertification audit, our company shall grant new certificate to certified organization, the valid period will be recalculated.

3.10 授與、維持、更新、增列、減列、暫時終止及終止驗證範圍的處置：執行 ARES-QP-03《授與、拒絕、維持、更新、暫時終止、恢復、或終止驗證、或增列或減列驗證範圍管制程序》的有關規定。Follow the rule of ARES-QP-03《 granting, refusing, maintaining, renewing, suspending, restoring, or withdrawing, expanding, reducing of certification scope control procedure》.

3.11 驗證要求的更改 Change of certification requirement

當驗證要求（如管理系統驗證標準換版）發生變化，本公司將要求獲證組織變更系統以適應驗證要求的變化，並實施稽核。對於新標準轉換，獲證組織應按適宜的新標準修改系統檔，並運行三個月，實施內部稽核和管理審查，本公司依據雙方簽訂的合約和驗證申請表，

對獲證組織依據新版本標準實施稽核通過後，換新版標準的證書，證書有效期為三年。
When the certification requirement changed (such as management system certification standard update to new version).Our company shall require certified organization adjust their management system to fit the changed standard, and then conduct audit activity. For new version standard transform, certified organization should adjust their system document in line with new version standard and implement their system at least 3 months, implement internal audit and management review. Our company will conduct certification according to new version standard base on contract and application. New version standard certificate will be granted after passed the certificated audit. New valid period will be recalculated.

4. 申請驗證組織/獲證組織的權利和義務 Right and responsibility of applicant/certified organization

4.1 權利 Right

4.1.1 驗證申請（委託）人有權瞭解驗證機構運作依據和驗證程序；Applicant have a right to know the certification procedure and basis of certification body perform.

4.1.2 有權索取有關驗證的說明和公開文件； Have a right to obtain certification illustration and public file.

4.1.3 有權對稽核計畫和稽核組成員提出異議，並得到合理解決； Have a right to suggest the audit plan and audit team, and got reasonable solution.

4.1.4 有權對稽核組提出的不合格事實進行確認； Have to right to confirm whether the non-conformity report which issued by audit team is a fact or not.

4.1.5 有權對稽核組工作和稽核結論提出質疑； Have a right to question the audit work or audit conclusion performed by our audit team.

4.1.6 驗證機構批准的正式稽核報告與稽核組的稽核結論有差異時，有權要求驗證機構作出解釋； Have a right to request certification body to explain the detail reason if the audit conclusion is different from final audit report.

4.1.7 當驗證機構將稽核／追查稽核分包給外部機構或人員時，有權提出意見，甚至不同意（應有正當理由）。 Have a right to give suggestion or don't accept at all(with a good reason) if certification body outsource other body to conduct audit.

4.1.8 有權正確使用驗證證書和標誌，有權登入驗證機構名錄並公告； Have a right to use the

certificate and logo, and also be registered and be open to public.

4.1.9 有權要求驗證機構保密和遵守本方的有關規定；Have a right to request certification body keep confidentiality and comply with their rule.

4.1.10 有權對驗證機構／人員提出申訴／抱怨； Have a right to appeal/complaint to the CB

4.1.11 有權要求驗證機構對其他有關驗證問題作出解釋或澄清。Have a right to request certification body to explain or clarify relevant certification issue.

4.2 義務 Responsibility

4.2.1 始終遵守驗證機構驗證稽核的有關程序規定和公開文件的要求； Should always abide by the audit procedure and the requirement of the public document

4.2.2 按期繳納費用（驗證不通過時也應繳納費用）； Should pay audit fee on time(when the audit didn't be passed, still need to pay the audit fee)

4.2.3 為驗證機構、認證單位進行的現場稽核、驗證、檢查、追查及重新驗證稽核和解決申訴做出必要安排；包括接受驗證機構的文件稽核，調閱所有記錄（包括客戶申訴）； Should provide necessary arrangement for certification body when they conduct on-site audit, verification, check ,surveillance, recertification or solve appeal activity. Include accepting document audit, obtain all record (include customer complain)

4.2.4 積極配合稽核，如實提供情況、說明、資料、文件、記錄；Should actively cooperate with audit, provide truthful, instructions, data, documents and records

4.2.5 正確使用驗證證書和驗證認證標誌，需就使用遵守在獲准驗證的範圍內作聲明； Should right use certificate and logo, should declare the use scope which be covered by certificate.

4.2.6 在宣傳驗證結果時不得損害驗證機構的聲譽，不得做出使驗證機構認為誤導或未授權的聲明；Shouldn't harm the reputation of the certification body when propaganda the certification result. Shouldn't miss lead or declare which didn't be authorized by certification body.

4.2.7 當驗證被暫時終止或終止時，應立即停止涉及驗證內容的宣傳，並按驗證機構要求交回所有驗證文件；When certification terminated temporarily or terminate, should terminate immediately propagandizing involved certificate content and return the entire certificate file as the certification body required.

5.亞瑞仕可開展的業務範圍包括：品質管理系統、環境管理系統、職業安全衛生

管理系統、有害物質過程管理系統、食品安全管理系統、醫療器材品質管理系統、資訊安全管理系統、台灣職業安全衛生管理系統、能源管理系統、化粧品優良製造準則(GMP)。ARES can be the scope of business include: Quality Management System, Environmental Management System, Occupational Health and Safety Management System, Hazardous Substances Process Management System, Food Safety Management Systems (FSMS), Medical Devices Quality Management Systems (MDQMS), Information Security Management Systems (ISMS), Taiwan Occupational Health and Safety Management System (TOSHMS), Energy Management System (EnMS), Cosmetics Good Manufacturing Practice Regulations(GMP).

5.1 品質管理系統、環境管理系統、職業安全衛生管理系統已認證的驗證範圍明細表如下：

Quality Management System, Environmental Management System, Occupational Health and Safety Management System. The accredited certification schedule is as follows:

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
01	農業、森林業及漁業 AGRICULTURE, HUNTING AND FORESTRY	✓	✓	✓			✓		
02	礦業及採集業 MINING AND QUARRYING								
03	食品、飲料和煙草 MANUFACTURE OF FOOD PRODUCTS; BEVERAGES AND TOBACCO	✓	✓	✓			✓		

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
04	紡織品和紡織製品 MANUFACTURE OF TEXTILES AND TEXTILE PRODUCTS	✓	✓	✓	✓				
05	皮革及皮革製品的製作 MANUFACTURE OF LEATHER AND LEATHER PRODUCTS								
06	木材及木製品 MANUFACTURE OF WOOD AND WOOD PRODUCTS	✓	✓	✓					
07	紙漿、紙及紙製品 MANUFACTURE OF PULP, PAPER AND PAPER PRODUCTS	✓	✓	✓					
08	出版業 Publishing								
09	印刷業 Printing and service activities related to printing	✓							
10	焦炭及精煉石油製品的製造 Printing and service activities related to printing								
11	核燃料 Processing of nuclear fuel								
12	化學品、化學製品及纖維 MANUFACTURE OF	✓	✓	✓	✓		✓		

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
	CHEMICALS, CHEMICAL PRODUCTS AND MAN-MADE FIBRES								
13	藥品 Manufacture of pharmaceuticals, medicinal chemicals and botanical products								
14	橡膠和塑膠製品 MANUFACTURE OF RUBBER AND PLASTIC PRODUCTS	✓	✓	✓	✓		✓	✓	
15	非金屬礦物製品 MANUFACTURE OF OTHER NON-METALLIC MINERAL PRODUCTS	✓	✓	✓					
16	混凝土、水泥、石灰、石膏及其他 Manufacture of cement, lime and plaster	✓							
17	基礎金屬及金屬製品 MANUFACTURE OF BASIC METALS AND FABRICATED METAL PRODUCTS	✓	✓	✓	✓	✓	✓	✓	
18	機械及設備 MANUFACTURE OF MACHINERY AND EQUIPMENT N.E.C.	✓	✓	✓	✓	✓	✓	✓	

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
19	電及光學設備 MANUFACTURE OF ELECTRICAL AND OPTICAL EQUIPMENT	✓	✓	✓	✓	✓	✓	✓	
20	造船業 Building and repairing of ships and boats								
21	航空航太 Manufacture of aircraft and spacecraft								
22	其他運輸設備 MANUFACTURE OF TRANSPORT EQUIPMENT				✓				
23	其他未分類製造業 MANUFACTURING N.E.C.	✓	✓	✓	✓		✓		
24	回收業 RECYCLING	✓	✓	✓					
25	供電業 Production and distribution of electricity	✓	✓	✓			✓		
26	供氣業 Manufacture of gas; distribution of gaseous fuels through mains		✓	✓					
27	供水業 Steam and hot water supply	✓	✓	✓					
28	建設業 CONSTRUCTION	✓	✓	✓			✓		
29	批發和零售業；汽車、摩	✓	✓	✓					

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
	托、個人及家庭用品的修理業 WHOLESALE AND RETAIL TRADE; REPAIR OF MOTOR VEHICLES, MOTORCYCLES AND PERSONAL AND HOUSEHOLD GOODS								
30	賓館及餐館 HOTELS AND RESTAURANTS	✓							
31	運輸、倉儲及通信業 TRANSPORT, STORAGE AND COMMUNICATION	✓	✓	✓					
32	金融仲介、房地產、租賃 FINANCIAL, INTERMEDIATION	✓	✓	✓			✓		
33	資訊技術 COMPUTER AND RELATED ACTIVITIES	✓	✓	✓					
34	工程服務 RESEARCH AND DEVELOPMENT	✓	✓	✓	✓	✓	✓		
35	其它服務 OTHER BUSINESS ACTIVITIES	✓	✓	✓					
36	公共行政管理 PUBLIC		✓	✓					

大類 Scope	內容 Description	IAS			TAF			UKAS	
		QMS	EMS	OH&SMS	QMS	EMS	OHSMS	QMS	EMS
	ADMINISTRATION AND DEFENCE; COMPULSORY SOCIAL SECURITY								
37	教育 EDUCATION		✓	✓					
38	健康和社會服務 HEALTH AND SOCIAL WORK	✓	✓	✓					
39	其他社會服務 OTHER COMMUNITY, SOCIAL AND PERSONAL SERVICE ACTIVITIES	✓	✓	✓			✓		
注：打“✓”的是 ARES 經認證的驗證業務範圍。The "✓" is ARES accredited certification scope. 注：ARES 台灣職業安全衛生管理系統驗證業務範圍同 TAF 職業安全衛生管理系統驗證業務範圍。									

5.2 食品安全管理系統已認證的驗證範圍明細表如下：The food safety management systems (FSMS) accredited certification schedule is as follows:

	類別 category	IAS	TAF
A	動物畜養 Animal husbandry	✓	
B	植物耕作 Plant cultivation	✓	
C	食品製造 Food manufacturing	✓	
D	動物飼料生產 Animal feed production	✓	
E	餐飲 Catering	✓	
F	經銷 Distribution		
G	提供運輸與儲存服務 Provide transport and		

	storage services		
H	服務 service		
I	食品包裝與包裝材料之生產 Food packaging and packaging materials production	✓	
J	設備之製造 Equipment manufacturing		
K	(生物)化學品之生產 (Biological) chemical production	✓	
注：打“✓”的是 ARES 經認證的驗證業務範圍。The "✓" is ARES accredited certification scope.			

5.3 醫療器材品質管理系統已認證的驗證範圍明細表如下：The Medical Devices Quality Management Systems (MDQMS) accredited certification schedule is as follows:

Main Technical Areas	**Technical Areas**	**Product Categories Covered by the Technical Areas**	
Non-active Medical Devices 非有源醫療設備	General non-active, non- implantable medical devices 一般非有源、非植入醫療設備	Non-active devices for anaesthesia, emergency and intensive care 麻醉、急診室和重症監護的非有源設備	✓
		Non-active devices for injection, infusion, transfusion and dialysis 注射、輸液、輸血和血液透析非有源設備	✓
		Non-active orthopedic and rehabilitation devices 非有源骨科和康復設備	✓
		Non-active medical devices with measuring function 非有源量測功能的醫療器械	✓
		Non-active ophthalmologic devices 非有源眼科設備	
		Non-active instruments 非有源儀器	✓
		Contraceptive medical devices 避孕醫療設備	
		Non-active medical devices for disinfecting, cleaning, rinsing 非有源進行消毒、清洗、漂洗的醫療器械	✓

		Non-active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) 非有源體外受精和輔助生殖技術的醫療器械	
		Non-active medical devices for ingestion 非有源用於攝食的醫療器械	
	Non-active implants 非有源植入物	Non-active cardiovascular implants 非有源心血管植入物	
		Non-active orthopedic implants 非有源骨科植入物	
		Non-active functional implants 非有源功能性植入物	
		Non-active soft tissue implants 非有源軟組織植入物	
	Devices for wound care 傷口護理設備	Bandages and wound dressings 繃帶和傷口敷料	
		Suture material and clamps 縫合材料和夾具	
		Other medical devices for wound care 傷口護理的其他醫療設備	
	Non-active dental devices and accessories 非有源牙科設備及其配件	Non-active dental devices / equipment and instruments 非有源牙科設備和儀器	
		Dental materials 牙科材料	

		Dental implants 牙科植入物	
	Non-active medical devices other than specified above 其他非有源醫療器械		✓
Active Medical Devices (Non- Implantable) 有源(非植入)醫療器械	General active medical devices 一般有源醫療器械	Devices for extra-corporal circulation, infusion and hemapheresis 體外循環、輸液和血液置換的裝置	
		Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia 呼吸裝置，包括用於氧氣治療，吸入麻醉的高壓艙的裝置	
		Devices for stimulation or inhibition 刺激或抑制裝置	
		Active surgical devices 有源手術設備	
		Active ophthalmologic devices 有源眼科設備	
		Active dental devices 有源牙科設備	
		Active devices for disinfection and sterilization 有源消毒和滅菌設備	

		Active rehabilitation devices and active prostheses 有源康復設備和有源假肢	
		Active devices for patient positioning and transport 有源患者定位和運輸設備	✓
		Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) 有源體外受精和輔助生殖技術的醫療器械	
		Software 軟體	
		Medical gas supply systems and parts thereof 醫用氣體供應系統及其部件	
	Devices for imaging 影像設備	Devices utilizing ionizing radiation 電離輻射設備	
		Devices utilizing non-ionizing radiation 非電離輻射設備	
	Monitoring devices 監控設備	Monitoring devices of non- vital physiological parameters 非重要生理參數監測設備	✓
		Monitoring devices of vital physiological parameters 重要生理參數監測設備	✓
	Devices for radiation therapy and thermo therapy	Devices utilising ionizing radiation 電離輻射的設備	

	放射治療和熱療設備	Devices utilising non-ionizing radiation 非電離輻射的設備	
		Devices for hyperthermia / hypothermia 高溫/低溫設備	
		Devices for (extracorporal) shock-wave therapy (lithotripsy) 用於（體外）衝擊波治療的設備（碎石術）	
	Active (non-implantable) medical devices other than specified above 其他有源設備(非植入)		
Active Implantable Medical Devices 有源(可植入)醫療設備	General active implantable medical devices 一般有源植入式醫療器械	Active implantable medical devices for stimulation / inhibition 主動植入式醫療設備，用於刺激/抑制	
		Active implantable medical devices delivering drugs or other substances 主動植入式醫療設備，可輸送藥物或其他物質	
		Active implantable medical devices substituting or replacing organ functions 有源植入式醫療設備替代器官功能	
	Implantable medical devices other than specified above 其他可植入醫療設備		

In Vitro Diagnostic Medical Devices (IVD) 體外診斷醫療器械	Reagents and reagent products, calibrators and control materials for 試劑和試劑產品，校準品和控製材料	Clinical Chemistry 臨床化學	✓
		Immunochemistry (Immunology) 免疫化學（免疫學）	✓
		Haematology/Haemostasis/ Immunohematology 血液學/止血/免疫血液學	✓
		Microbiology 微生物學	✓
		Infectious Immunology 傳染性免疫學	✓
		Histology/Cytology 組織學/細胞學	✓
		Genetic Testing 基因檢測	✓
	In Vitro Diagnostic Instruments and software 體外診斷儀器和軟體		
	IVD medical devices other than specified above 其他體外診斷醫療器械		
Sterilization Method for Medical Devices 對醫療器械的滅菌方式	Ethylene oxide gas sterilization (EOG) 環氧乙烷氣體滅菌		✓
	Moist heat 濕熱滅菌		
	Aseptic processing 消毒處理		
	Radiation sterilization (e.g. gamma,		

	x-ray, electron beam) 輻射滅菌（例如伽馬，X 射線，電子束）		
	Sterilization method other than specified above 其他醫療器械的滅菌方式		
Devices incorporating/utilizing specific substances/ technologies 包含/利用特定物質/技術的設備	Medical devices incorporating medicinal substances 含有藥用物質的醫療器械		
	Medical devices utilizing tissues of animal origin 利用動物組織的醫療器械		
	Medical devices incorporating derivates of human blood 包含人類血液衍生物的醫療器械		
	Medical devices utilizing micromechanics 利用微力學的醫療器械		
	Medical devices utilizing nanomaterials 利用奈米材料的醫療器械		
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed 利用生物活性塗層和/或材料或被全部或主要吸收的醫療器械		

	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above. 其他包含/利用特定物質/技術/元素的醫療器械		
Parts or services 零件和服務	Raw materials 原料		✓
	Components 組件		✓
	Subassemblies 分段裝配		✓
	Calibration services Organizations providing calibration services should be accredited to ISO/IEC) 校準服務 (提供校準服務的組織應獲得 ISO/IEC17025 認可)		
	Distribution services 配送服務		
	Maintenance services 維修服務		
	Transportation services 運輸服務		
	Other services 其他服務		

注：打“✓”的是 ARES 經認證的驗證業務範圍。The "✓" is ARES accredited certification scope.	

5.4 能源管理管理系統已認證的驗證範圍明細表如下：The energy management systems (EnMS) accredited certification schedule is as follows:

技術領域 Technical	描述 Description	範例 Example	典型能源用途 Typical energy use	
輕至中型工業 Industry – light to medium	生產消費性中間產品或終端使用者為主產品之製造設施 Manufacturing facilities producing consumer intermediates or end user oriented products	衣物 clothing 消費性電子產品 consumer electronics 家電用品，傢俱 home appliances, furniture 塑膠品 plastics 定製品 fabrication 特殊化學品 speciality chemicals 食品加工 food processing 水及廢水處理 water and wastewater treatment	過程加熱(電力、天然氣、煤或其他來源) process heating (electricity, natural gas, coal or other source) 機器驅動(幫浦、風扇壓縮空氣、材料處理) machine drive (pumps, fans, compressed air, materials handling) 蒸氣系統 steam systems 小型冷卻水塔 small cooling towers 其他過程使用 other process uses 建築物能源使用(照明、 高壓交流電、熱水、可攜式裝置) building energy uses (lighting, HVAC, hot water, portable devices)	✓
重工業 Industry – heavy	需有高資本額及消耗大量原料與能源的製造設施 Manufacturing facilities requiring high capitalization and consuming large quantities of raw materials and energy	化學品 chemicals 鋼與金屬 steel and metals 煉油 oil refining 造船 ship-building 紙漿及造紙廠 pulp and paper mills 工業機械 industrial machinery	過程加熱(電力、天然氣、煤或其他來源、原料、中間產品) process heating (electricity, natural gas, coal or other source, raw materials, intermediates) 過程冷卻及冷藏 process cooling and refrigeration 機器驅動(幫浦、風扇壓縮空氣、	✓

		半導體 semiconductors 水泥及陶瓷業 cement and ceramic	材料處理) machine drive (pumps, fans, compressed air, materials handling) 渦輪、冷凝器 turbines, condensers 蒸氣系統 steam systems 運輸 transportation	
大樓 Buildings	具標準商業大樓實務之設施 Facilities with standard commercial building practices	辦公室 offices 住所 lodging 零售 retail 倉庫 warehouse	可攜式裝置 portable devices 水加熱 water heating 照明 lighting 暖氣與冷氣系統、相關的風扇 heating and cooling systems, related fans 幫浦系統 pumping systems	
複合式大樓 Building complexes	由於能源來源與使用的複雜性，操作需有特定專業 知識之設施 Facilities with operations requiring specific expertise due to the complexity of energy sources and uses	醫療設施 health care facilities 實驗室 laboratories 資料中心 data centers 校園 educational campuses 整合能源供應的軍事及政府園區 (分區暖氣與冷氣) military and government campuses with integrated energy supply (district heating and cooling) 市政府 municipalities	中央及分區暖氣與冷氣系統 centralized and district heating and cooling systems 可攜式裝置 portable devices 水加熱 water heating 照明 lighting 局部高壓交流電 local HVAC 壓縮空氣、材料處理系統 compressed air, materials handling systems 電梯/升降梯 elevator /lifts	

運輸 Transport	運送人員或商品/貨物之系統工具 System or means for transporting people or goods/cargo	載客服務(汽車、火車、船、飛機) passenger services (vehicle, train, ship, airplanes) 市政府 municipalities 貨運服務 trucking services 車隊 fleets 鐵路作業 rail operations 遊輪 cruise lines 航空公司、空運 airlines, airfreight 船隊 fleets	行動能源使用 mobile energy uses 高壓交流電 HVAC 照明 lighting 可攜式裝置 portable devices 材料處理 materials handling 燃料源(燃油、電力、煤等) sources (fuel oil, electricity, coal, etc.)	✓
礦業 Mining	露天煤礦、原料之地下及流體開採及運輸 Open cast, underground and fluid extraction of raw materials and transport	礦物分離 mineral separation 濕法冶金術 hydrometallurgy 熔煉及精煉 smelting and refining 石油及天然氣探鑽作業 oil and gas drilling operations 瓦斯與石油管線 gas and oil pipelines	萃取 extraction 運輸(裝貨機、卡車及輸送帶) transportation on (loaders, trucks, and conveyors) 機器驅動(抽水、通風、渦輪、風扇) machine drive (water pumping, ventilation, turbines, fans) 材料製備(碾碎、研磨、分離) materials preparation (crushing, grinding, separation) 蒸氣系統、冷凝器及冷卻水塔 steam systems, condenser and cooling towers	

農業 Agriculture	家畜、播種或作物產品 Livestock, seed or crops products	耕作 farming 播種生產 seed production 材料之搬運 hauling of materials 動物生產 animal production	萃取 extraction 燃料源(燃油電力、天然氣、煤等) sources (fuel oils electricity, natural gas, coal, etc.) 再生能源(生質、太陽能、地熱等) renewables (biomass, solar, geothermal, etc.) 運輸 transport 電動機 motors 驅動器(幫浦、風扇、材料處理) drives, (pumps, fans, material handling) 幫浦 pumps 水處理 water treatment 乾燥器 dryers	
能源供應 Energy supply	能源產生(核能、CHP、電力、再生 等)及運輸(傳輸及分配) Energy generation (nuclear, CHP, electricity, renewable, etc.) and transport (transmission and distribution)	發電(煤、油、天然氣、再生能源、CHP、IGCC 等) power generation (coal, oil, natural gas, renewable, CHP, IGCC, etc.)	原料轉變 raw materials transformation 傳輸及分配渦輪 transmission and distribution turbines 燃燒 combustion 蒸氣系統 steam systems 冷凝器及冷卻水塔 condenser and cooling towers	
注：打“✓”的是 ARES 經認證的驗證業務範圍。The "✓" is ARES accredited certification scope.				

5.5 資訊安全管理系統已取得認證的範圍如下：The information security management systems (ISMS) accredited certification schedule is as follows:

AB	IAS	TAF
已取得認證 Accredited	✓	✓