



台灣檢驗科技股份有限公司-健康產業服務
SGS Taiwan Ltd. - Health Industry Services
超微量工業安全實驗室委託試驗申請書- 醫療器材(ISO 18562)試驗

Ultra Trace and Industrial Safety Hygiene Laboratory Application Form - Medical Device (ISO 18562) Test

填妥後·請傳真至地區窗口：□台北：02-22981338 □台中：04-23592949 □高雄 07-3010860

申請廠商 (APPL./Sponsor) 試驗委託者	*申請廠商 APPL. :
	*申請廠商地址 APPL. Address :
	*申請廠商電話 APPL. Tel : 分機 Ext :
	*申請廠商聯絡人 Contact Person :

※粗框中標示「*」符號的內容將呈現於報告中·The contents marked with 「*」 will be shown in the report.

發票廠商 Invoice	報告聯絡電話 Tel : 分機 Ext :
	傳真 Fax : 行動門號 Mobile :
	電子郵件 E-mail : 聯絡人 Contact Person :

發票廠商 Invoice	發票廠商 Invoice To :
	發票郵寄地址 Registration Address :
	統一編號 Registration Add. I/V No :
	電話 Tel : 分機 Ext :
	傳真 Fax : 行動門號 Mobile :

電子郵件 E-mail : 付款聯絡人 Contact Person :

※如申請廠商/試驗委託者與發票廠商不同·需提供附件一“付款切結書”·The payment statement should be provided if the invoice title is different as the applicant.

*報告抬頭廠商及地址 Company name and address in the report (必填 required) :

同申請廠商/試驗委託者 As applicant / sponsor 同發票廠商 As Invoice company

其他抬頭廠商 As below : 報告抬頭廠商 Sponsor's Name :

報告抬頭地址 Sponsor's Address :

※粗框中標示「*」符號的內容將呈現於報告中·The contents marked with 「*」 will be shown in the report.

報告格式 Report format (請勾選 Please pick) : 中文報告電子檔 Soft Copy (Traditional Chinese) 英文報告電子檔 Soft Copy (English)

申請加發紙本報告 Hard Copy : 中文 Traditional Chinese 英文 English

紙本報告取法 Shipping Method of Hard Copy :

自取報告 Pick up by self 報告普掛郵寄及其地址 By mail. Recipient's Address : □□□-□□□

※檢測僅提供一種語言報告電子檔；若同時選擇中、英二種語言電子檔或申請加發紙本報告·需額外收取費用·如勾選申請加發紙本報告·務必勾選報告取法；紙本報告只限台灣境內寄送·We will provide a soft copy in one kind of language (either Chinese or English) for free. Additional soft copy or hard copy will be charged. Please select and tick. Please select the method to have the reports. A hard copy is for domestic mail in Taiwan only.

普通件 General 急件(費用加 50%) Express (Surcharge 50%) 特急件(費用加 96%) Urgent (Surcharge 96%)

※收件當天及例假日不列入工作天數·For Express & Urgent service, please inform us in advance. Working days non-including weekends and National holidays. (若未勾選一律以普件處理 Default for General)

樣品資訊 Sample Information	1.*產品名稱 Sample Name (必填 required) :
	2.*□製造日期 MFG : *□有效期限 EXP : *□批號 Lot. No. : □型號 Model No. :
	3.*檢測單件樣品量 Amount (必填 required) : 數量 Quantity _____ / 單位 Unit _____
	<small>(若勾選“散裝”請提供總重量·If "Bulk" is checked, please provide the total weight.)</small>
	4.*包裝狀態 Packing Condition : <input type="checkbox"/> 完整包裝 Intact Packing <input type="checkbox"/> 散裝 In Bulk
	5.*製造/國內負責廠商 Supplier/Manufacturer (必填 required) :
	6.*樣品保存方式 Storage Condition : <input type="checkbox"/> 冷凍-15°C~-25°C <input type="checkbox"/> 冷藏 2°C~8°C <input type="checkbox"/> 室溫 Room Temperature
	7. 測項及報告使用目的 Testing purpose :

自主管理 For self-management 出口使用 For export 符合政府法規要求 For regulations

8. 其他 Others :

※若申請廠商非送測產品的生產製造商或品牌所有者·請填寫附件二“委託檢測聲明書”·或提供相關合作授權證明·The letter of commissioned inspection statement of authorization or relevant cooperation authorization certificate is necessary if the applicant is not the manufacturer or brand owner of the product submitted for testing.
※以上“必填”欄位若未填寫視同無·報告則將出具“-”。包裝上標示(製造/有效日期/型號/批號/生產或供應商)資訊會拍照呈現報告中·粗框中標示「*」符號內的內容將呈現於報告中·Please noted that if the content marked as "*" is blank, there will be issued as "-" in the report. Please noted that any information on the package (includes manufacture date / expiry date / model number / lot number / supplier or manufacturer) will be shown with the sample photo in the report. Please noted that the contents marked as "*" will be shown in the report.

報告號碼(Report No): _____ (此欄位由 SGS 填寫 Written by SGS staff)

委託實驗項目 (Test(s) Required) :

產品敘述

- | | | |
|---|-------------------|--|
| 1 | 產品使用族群
(請擇一勾選) | <input type="checkbox"/> Adult <input type="checkbox"/> Children <input type="checkbox"/> Neonates <input type="checkbox"/> 其他(未在表列請自行填寫)_____ |
| 2 | 使用週期 | <input type="checkbox"/> ≤24 小時 <input type="checkbox"/> > 24 小時~30 天 <input type="checkbox"/> > 30 天 |
| 3 | 累積暴露量 | <input type="checkbox"/> <30 天 <input type="checkbox"/> > 1 個月~12 個月 <input type="checkbox"/> > 1~10 年 <input type="checkbox"/> > 10 年 |
| 4 | 器材使用 | <input type="checkbox"/> 不可於醫療院所外使用 <input type="checkbox"/> 可於醫療院所外使用 |

ISO 18562 測試項目

ISO 18562-2 Emissions of particulate matter (執行 24 小時)

- | | | |
|---|------------|--|
| 1 | 氣體以空氣進行實驗。 | |
| 2 | 氣體流速 | <input type="checkbox"/> _____ m ³ /min <input type="checkbox"/> _____ m ³ /d。 |

ISO 18562-3 Emissions of volatile organic compounds (VOCs)

- | | | |
|---|------------|--|
| 1 | 氣體以空氣進行實驗。 | |
| 2 | 氣體流速 | <input type="checkbox"/> _____ m ³ /min <input type="checkbox"/> _____ m ³ /d。 |
| 3 | 通氣時間 | _____ min |

ISO 18562-4 Tests for leachables in condensate

- | | | |
|---|------|---|
| 1 | 萃取條件 | 溫度: _____ °C 時間: <input type="checkbox"/> _____ 小時 <input type="checkbox"/> _____ 天 |
| 2 | 萃取溶劑 | _____ |

- | | | |
|---|------|---|
| | | (1.) <input type="checkbox"/> 以冷凝水萃取;
氣體: <input type="checkbox"/> 氧氣 <input type="checkbox"/> 空氣 <input type="checkbox"/> 其他(未在表列請自行填寫)_____。
氣體流速 _____ m ³ /min。 |
| 3 | 萃取方式 | (2.) <input type="checkbox"/> 僅萃取管路內側
表面積萃取: <input type="checkbox"/> (3±10%)cm ² /mL <input type="checkbox"/> (6±10%)cm ² /mL · 表面積為 _____ cm ² 。
(3.) <input type="checkbox"/> 全樣浸泡
表面積萃取: <input type="checkbox"/> (3±10%)cm ² /mL <input type="checkbox"/> (6±10%)cm ² /mL · 表面積為 _____ cm ² 。
(4.) <input type="checkbox"/> 其他(未在表列請自行填寫)_____ |

- | | | |
|---|----|--|
| 4 | 儀器 | <input type="checkbox"/> GC/MS scan <input type="checkbox"/> LC/QTOF scan <input type="checkbox"/> ICP/MS scan <input type="checkbox"/> 其他(未在表列請自行填寫)_____ |
|---|----|--|

備註: _____

報告號碼(Report No): _____ (此欄位由 SGS 填寫 Written by SGS staff)

備註及聲明 Note and Statement

1. 本申請廠商/試驗委託者申請上述之檢驗，同意所有試驗依 SGS 所訂之通用服務條款(<http://www.sgs.com.tw/Terms-and-Conditions>)履行。The applicant/sponsor applies for the above-mentioned inspection and agrees that all tests should be conducted in accordance with the 「GENERAL CONDITIONS OF SERVICE」 stipulated by SGS (<http://www.sgs.com.tw/Terms-and-Conditions>).
2. 如未附報價單，以 SGS 定價為主。If no quotation is attached, the SGS pricing shall prevail.
3. 此檢驗費用均為未稅金額；新交易、久未交易(一年內未有交易往來)及海外客戶需先付清款項，方能執行檢驗。The inspection fee is the tax-excluded amount. For long-term transactions (no transaction within one year) and overseas customers, please make the remittance prior to the testing.
4. 微生物參照衛生福利部公告方法檢驗；微生物不接受急件、特急件。Microorganism testing refers to International Standard or Official methods. Express and Urgent services are not available for microorganism testing.

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5. 申請廠商/試驗委託者所提供的測試樣品/試驗物質/對照物質會因取樣與測試需要，而造成測試樣品/試驗物質/對照物質之減損與破壞。若委託者不同意或有特殊要求時，應主動於申請檢測前告知並載明於申請書。若因申請廠商/試驗委託者未告知而產生相關損失，本實驗室將不負賠償責任。對於送驗之測試樣品/試驗物質/對照物質依樣品類型留存至少一周(依報告簽署日後起算)，除非申請廠商/試驗委託者另有要求且記載於申請書上，將另作處置。(依據本實驗室之樣品保存規範) The test samples/ test article/control article provided by the applicant/sponsor might be damaged or destroyed due to sampling and testing requirements. If the applicant/sponsor does not agree or has special requirements, should take the initiative to inform and specify it in the application form prior to the test. If the applicant/sponsor doesn't inform and causes relevant losses, we will not be liable for compensation. The test samples/ test article/control article submitted for testing shall be kept for at least one week according to sample type (from the date of issuing the report) unless otherwise required by the applicant/sponsor and recorded on the applicant/sponsor form, they will be processed separately. (According to our sample storage specification)
6. 若測試樣品/試驗物質/對照物質(或方法)被判斷為偏離而申請廠商/試驗委託仍需檢測，將於報告中載明偏離事項。If the test samples/ test article/control article (or method) is judged to be deviated, the deviation will be stated in the report if the applicant/sponsor instructs to keep on the testing.
7. 不同種類、來源及最小獨立包裝之測試樣品/試驗物質/對照物質，應分別執行檢驗並出具報告，故本實驗室不接受多種產品混測執行。Test samples/test substances/control substances of different types, sources and smallest independent packaging should be tested separately and separated reports should be issued, so mixed testing of multiple products is not allowed.
8. 對任何委託之測試樣品/試驗物質/對照物質或實驗中包含任何已知的實際或潛在危險或危害，如放射性、有毒、有害、感染性物質(如病毒、病原體、動物檢體等)或爆炸元素或物質、環境汙染或中毒的存在和危險，需事先通知本實驗室。For any test samples/test substances/control substances or experiments that contain any known actual or potential dangers or hazards, such as radioactive, toxic, harmful, infectious substances (such as viruses, pathogens, animal samples, etc.), explosive elements or substances, or the existence and danger of environmental pollution or poisoning must be notified in advance.
9. 申請廠商/試驗委託者應確認所提供之測試樣品/試驗物質/對照物質/標準品等是否為管制藥品或毒性及關注化學物質，若是須提供相關登載及佐證文件以利與當地衛生主管機關、食品藥物署或行政院環境保護署申報。The applicant/sponsor shall confirm whether the provided test samples/ test article/control article/standards provided are Controlled Drug or Toxic and Concerned Chemical Substances and shall provide relevant registered and supporting documents to facilitate declaration with local health authority, Taiwan Food and Drug Administration or the Environmental Protection Administration, Executive Yuan.
10. 申請廠商/試驗委託者有提供之試驗過程必要之資訊(包含但不限於對照物質、管柱、與當次測試結果相關之計算數據)，應同步提供該合用性之成份分析檢驗報告或聲明書。The applicant/sponsor shall provide the necessary information for the test process (including but not limited to reference substances, columns, and analytical data related to the current test result), and shall provide the COA (Certificate of Analysis) or statement of the suitability at the same time.
11. 報告所載測試結果將依照法規、方法或認證證書所載之單位呈現，除內毒素因法規要求會換算於備註之外，其他測試項目不於報告中登載單位換算後的結果。The test results contained in the report will be presented in accordance with the regulations, methods or the units listed in the certification certificate. Except for endotoxin, which will be converted in the remarks due to regulatory requirements, other test items will not be published in the report after unit conversion.
12. 測試樣品/試驗物質/對照物質不退樣；若客戶需退樣，請於送件時通知本實驗室，測試樣品/試驗物質/對照物質的一致性、生物安全之責任及快遞費用由客戶負擔。The test samples/ test article/control article will not be returned; if the customer needs to return the test samples/ test article/control article, please notify us when sending the package. The responsibility of consistency and biosafety of the test samples/ test article/control article and courier fee shall be borne by the customer.
13. 本單位不於報告中呈現符合性聲明。We do not present a statement of conformity in the report.
14. 本檢測報告結果僅代表申請廠商/試驗委託者送測時的單一測試樣品/試驗物質/對照物質，不代表及涵蓋該廠商其他產品範疇。The results of this test report only represent a single test sample/ test article/control article submitted by the applicant/sponsor for testing, and do not represent and cover other product categories of the manufacturer.
15. 報告檢驗項目需與申請書勾選填寫之委託實驗項目一致相符；一份申請書只含一份報告；如不同申請書，需各別提供足量樣品。The test projects in the report must consist with the entrusted experiments ticked and filled in the application form; one application form only yields one report; if different application forms are required, sufficient test samples must be provided separately.
16. 申請廠商/試驗委託者若欲提出文件之轉出/延長/銷毀，應於委託案件時同時提出，若未提出，本實驗室不負相關保存責任；另文件超過歸檔保存期限，本實驗室即進行銷毀。If the applicant/sponsor would like to propose the transfer/extend/destroy of the documents, it should be submitted at the same time when writing down the application form. If not submitted, we shall not be responsible for the relevant preservation; if the document exceeds the archiving period, we will destroy it immediately.
17. 實驗室承諾，除法律要求外，對在執行實驗室活動中所獲得或產生的所有資訊予以保密。We undertake to keep confidential all information obtained or generated during the execution of laboratory activities, expect as required by law.
18. 申請廠商/試驗委託者同意授權受託機構處理外部服務轉件事宜並同意本實驗室回報委託案部分資訊予 TAF、TFDA 與相關法規單位。#表示為外部服務項目。The applicant/sponsor agrees to authorize us outsourcing the test and reporting some information of the test to TAF, TFDA and relevant regulatory authorities. # stands for subcontract.
19. 因申請書版面限制，無法於申請書上明述實驗方法與檢驗範圍等相關資訊，如您需要確認實驗方法與檢驗範圍等相關資訊時，煩請至網路連結(<https://msn.sgs.com/?c=H12A0>)查詢或掃描右方的 QR Code。Due to the page limitation of the application form, relevant information such as the experimental methods and inspection scope cannot be clearly stated one the application form. If you need to confirm the detailed information, please go to the Internet link (<https://msn.sgs.com/?c=H12A0>) or scan the QR Code on the right.
20. 申請廠商/試驗委託者同意申請書內之說明事項及送測資訊，並對所提供之資訊自行負責並承擔。The applicant/sponsor agrees to the explanations and testing information in the application form, and is responsible and responsible for the information provided.





台灣檢驗科技股份有限公司-健康產業服務
SGS Taiwan Ltd. - Health Industry Services
超微量工業安全實驗室委託試驗申請書- 醫療器材(ISO 18562)試驗

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21. 本申請書視同合約書。本申請書經「申請廠商/試驗委託者」及「本實驗室」雙方人員簽名確認後，視同本合約即刻生效。This application form is considered as a formal contract. After this application form has been signed and confirmed by the "applicant/sponsor" and "SGS Taiwan", it is deemed that the contract will take effect immediately.
22. SGS 擁有變更及保留本申請書服務內容之主動權利。SGS 亦同時保有是否承接案件之主動權利。SGS has the initiative right to change or retain the service content of this application., and SGS also has the initiative right to accept the case.

申請廠商/試驗委託者(聯絡人)親筆簽名或蓋公司章

Applicant/Sponsor (Contact Person) signed: (Please sign here)

簽署日期 Date (YYYY.MM.DD):

樣品及檢測方法是否偏離 if the sample or test method are deviated :

(此欄位由 SGS 填寫 Written by SGS staff)

無 No 有，偏離原因請說明並通知客戶。Yes，reason and inform the customer.

樣品破損 Sample / Product Package damage 樣品失溫 Temperature loss

樣品包裝不符檢測要求 Sample packing does not meet the requirement 檢測方法非最新版本 Test method is not a latest version

檢測方法擴充原方法適用基質 The test methods would be shown "extension" due to the specific matrix which not applied for the original method.

其他 Others _____

報告號碼(Report No):

Date in:

Date out:

付款切結書

※ 如第一頁申請廠商與發票廠商不同，再請填寫用印此付款切結書，

本公司_____ (申請廠商)於民國____年____月____日，送驗_____

(樣品名稱)至台灣檢驗科技股份有限公司檢驗，因公司內部因素，發票&付款由

_____ (發票廠商)支付。

若日後因上列之原因，造成台灣檢驗科技股份有限公司出具之報告

後，有任何付/收款問題、法律訴訟或名譽受損等問題，一律由本公司

_____ (申請廠商)負擔責任問題。

申請廠商之公司大小章

承辦人簽名：

用印處：

付款廠商之公司大小章

承辦人簽名：

用印處：

民國____年____月____日

委託檢測聲明書

※如第一頁申請廠商非送測產品的生產製造或品牌所有者，需填寫與用印此聲明書，

本公司_____ (申請廠商)於民國____年____月____日，受
_____公司委託，送_____產品至台灣檢驗科技股份有限公司檢驗，因本公司與客戶協定關係，測試報告上資料需如下呈現：

※報告廠商抬頭需填寫_____

※生產或供應廠商需填寫_____

※產品名稱需填寫_____

以上所有資料均取得此公司同意，

若日後因上列之原因，造成台灣檢驗科技股份有限公司出具之此份報告，有任何法律訴訟或名譽受損之疑，一律由本公司_____ (申請廠商)負擔責任問題。

申請公司經辦人_____

用印處：

申請公司簽章(大小章)_____

委託公司經辦人_____

用印處：

委託公司簽章(大小章)_____

民國____年____月____日

提供服務據點如下：

248020 新北市新北產業園區五權七路 38 號

台灣檢驗科技股份有限公司

超微量工業安全實驗室 _____ 收

Tel: 02-2299-3279 #7122~7124, #7129, #7131

Fax: 02-2298-1338

407271 台中市台中工業區 14 路 9 號

台灣檢驗科技股份有限公司

超微量工業安全實驗室 _____ 收

Tel : 04- 2359-1515 #1500~1502, #1505

Fax: 04-2359-2949

811637 高雄市楠梓加工出口區開發路 61 號

台灣檢驗科技股份有限公司

超微量工業安全實驗室 _____ 收

Tel : 07-3012121#4800~4805, #4809

Fax: 07-3010860

SGS 申請檢測流程 <<客戶須先付清檢驗款項>>

1. 填妥申請書。
2. 回傳申請書 mail 或傳真給客服人員，客服會 mail 正式報價單並確認所需樣品量、匯款帳號。
3. 請準備足夠之樣品與申請書(簽名)+報價單(簽名) +匯款收據(影本)，一併寄至 SGS。
4. SGS 收到您的樣品後，客服人員將 mail 收樣通知：正式報價單(含報告編號)、預出日期。
5. 完成檢測後，SGS 會寄草稿報告電子檔或傳真給 貴公司。
6. 請客戶確認草稿報告內容電子檔或傳真，若有任何問題請回覆 mail 或傳真，客服人員將協助您處理。
7. 若無問題將不用回覆，SGS 將於次一工作日提供電子簽章之報告電子檔(即為正式報告)，並於次二至三工作日寄出電子發票。
8. 如電子簽章之報告電子檔寄出日為月底(含發票截止日)，敝司也將會於下個月初另寄出電子發票。
9. 完成整個檢測流程，祝福您檢測順心。

備註: 依成品(含完整包裝)檢驗

※若同時檢測微生物與其他測項，煩請提供兩瓶(包)以上之樣品，以避免延誤出報告之時間。

※若無法提供兩瓶(包)以上之樣品，敝單位將會延 2~3 個工作天，以便其它測項之檢測。