STC

进口化妆品注册
备案服务

Imported Cosmetics Registration & Filing Service

www.stc.group

公司简介
COMPANY PROFILE

STC 是一间独立、非牟利的测试、检验及认证机构，总部设于香港。自 1963 年成立以来，STC 为世界各地的客户提供专业的一站式符合性评估服务，助产品顺利进入全球市场。

STC 作为跨国机构，除在中国广东、上海、常州、广西等多个城市或地区成立分公司外，环球网络已延伸至越南、日本、美国及德国。STC 拥有先进的实验室，并广受国际认可，可满足业内广泛需求。

广东省标检产品检测认证有限公司于 2019 年取得国家药品监督管理局化妆品注册和备案检验检测机构的资质，成为化妆品注册和备案检验检测机构之一，可承担化妆品检验检测工作。

Established in 1963, STC is an independent, not–for–profit testing, inspection and certification organization headquartered in Hong Kong. We offer one–stop professional conformity assessment services to clients around the world to help them enter global markets.

As an organization with a global network, not only has STC set up testing facilities and customer service offices in China's major cities such as Guangdong, Shanghai, Changzhou, Guangxi, but also in countries like Vietnam, Japan, the USA and Germany. Our world–class, internationally–accredited testing facilities can meet the needs of a wide range of industries.

STC (Guangdong) Company Ltd. obtained the testing agent qualification from the National Medical Products Administration in 2019, becoming one of the cosmetic registration and filing inspection and testing institutions, capable of undertaking cosmetic inspection and testing work.

检验检测机构资质认定 (CMA)

China Metrology Accreditation (CMA)

中国合格评定国家认可委员会 (CNAS)

China National Accreditation Service for Conformity Assessment (CNAS)

OECD 成员国墨西哥 GLP 监管署

ema–Mexican Accreditation Body (OECD GLP)

实验动物使用许可证

Laboratory Animal Use Permit

国家药品监督管理局化妆品注册和备案检验检测机构

Cosmetics Registration and Filing Inspection and Testing Institution of the National Medical Products Administration

愿景
Vision

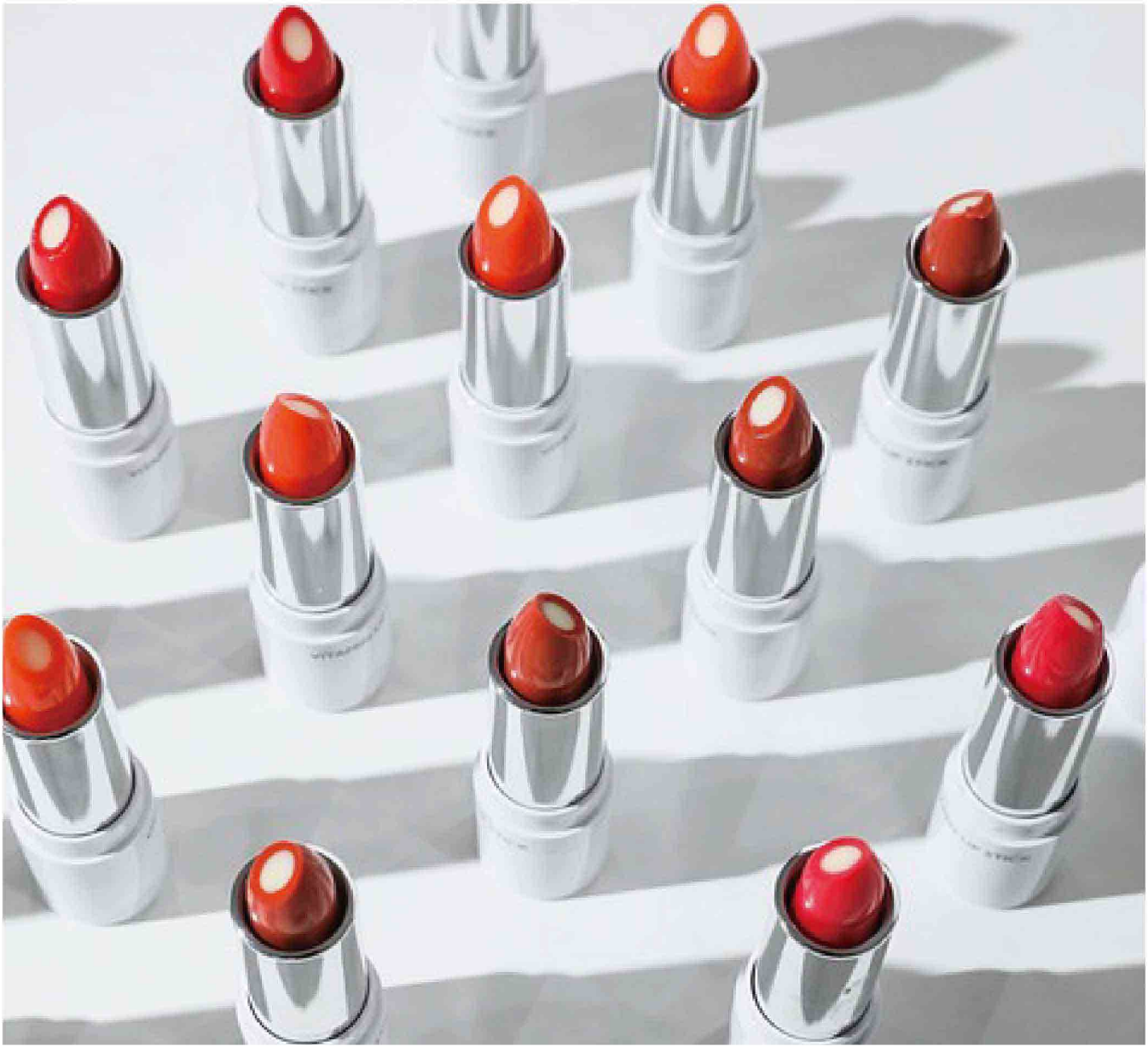
成为全球首屈一指，备受尊崇及认可的检测机构。

To become a leading conformity assessment service provider
that is recognized and respected worldwide.

化妆品
COSMETICS

根据国家药品监督管理局（NMPA）发布的《化妆品监督管理条例》，化妆品指的是以涂擦、喷洒或者其他类似方法，适用于皮肤、毛发、指甲、口唇等人体表面，以清洁、保护、美化、修饰为目的的日用化学工业产品。

According to the Cosmetic Supervision and Administration Regulation (CSAR) issued by the National Medical Products Administration (NMPA), cosmetics refer to daily used industrial chemical products, which can be used on the outer surface of the human body, including skin, hair, nails and lips, for the purpose of cleaning, protecting, beautifying and making up, by way of smearing, spraying or other similar means.



特殊化妆品 Special Cosmetics

用于染发、烫发、祛斑美白、防晒、防脱发的化妆品以及宣称新功效的化妆品，进口前需要按照 NMPA 的要求进行产品注册。

Cosmetics used for hair dyeing, hair perming, spot removal, whitening, sun protection and hair loss prevention, as well as cosmetics claiming new efficacy, need to undergo product registration according to the requirements of the NMPA before being imported.

普通化妆品 General Cosmetics

除特殊化妆品以外的化妆品 (如香水、护发等)，进口前需要按照 NMPA 的要求进行产品备案。

Cosmetics other than special cosmetics (such as perfumes, hair care products, etc.) shall complete the filing according to the requirements of the NMPA before being imported.

进口化妆品的定义
DEFINITION OF IMPORTED COSMETICS

化妆品最后一道接触内容物的工序在境内完成的为国产产品，在境外完成的为进口产品，在中国台湾、香港和澳门地区完成的按照进口产品管理。(包含两个或者两个以上必须配合使用或者包装容器不可拆分的独立配方的化妆品，其中一个 (剂) 或者多个 (剂) 产品在境外生产的，应当按照进口化妆品申请注册或者办理备案。)

Domestic products refer to cosmetics where the final contact process with the contents is completed within the country, while imported products refer to those where this process is completed overseas. Cosmetics manufactured in the Hong Kong, Macao and Taiwan regions of China are managed as imported products. (For cosmetics containing two or more independent formulas that must be used together or are packaged in inseparable containers, and where one or more products are manufactured overseas, registration or filing as imported cosmetics is required.)

进口化妆品注册/备案需要进行的测试项目

TESTING ITEMS REQUIRED FOR REGISTRATION / FILING OF IMPORTED COSMETICS

根据《化妆品安全技术规范》与《化妆品注册和备案检验工作规范》的要求，对送检样品进行安全性检验。化妆品备案相关测试项目包括微生物与理化检验、毒理学试验和人体安全性与功效评价检验等测试项目。

According to the requirements of the Safety and Technical Standards for Cosmetics and the Work Specifications for Cosmetics Registration and Record–filing Inspection, safety tests are conducted on samples submitted for inspection. Cosmetic registration–related testing items include microbiological and physicochemical tests, toxicology tests, and tests for human safety and efficacy evaluation.

- 微生物和理化检验：菌落总数、霉菌和酵母总数、耐热大肠菌群、金黄色葡萄球菌、铜绿假单胞菌、铅、砷、汞、镉。

  Microbiological and physicochemical tests: total bacterial count, total mold and yeast count, heat–resistant coliforms, Staphylococcus aureus, Pseudomonas aeruginosa, lead, arsenic, mercury, cadmium.

- 风险物质检测报告：根据配方确定是否有如二噁烷、石棉等有害物质。

  Risk substance detection report: determine whether hazardous substances such as dioxane, asbestos, and others are present based on the formula.

- 毒理检验：根据产品用途和类别进行相应的毒理性检验。(儿童化妆品应当通过安全评估和必要的毒理学试验进行产品安全性评价。)

  Toxicological testing: conduct appropriate toxicological assessments based on the product's purpose and category. (Children's cosmetics should undergo safety assessments and necessary toxicology tests for product safety evaluation.)

- 人体安全性和功效评价：普通化妆品按照《化妆品功效宣称评价规范》进行功效评价。

  Human safety and efficacy evaluation: general cosmetics are evaluated for efficacy according to the *Standard for the Evaluation of Efficacy Claims of Cosmetics*.

进口化妆品注册备案流程
IMPORTED COSMETICS REGISTRATION & FILING PROCESS

进口普通化妆品备案流程
Imported General Cosmetics Filing Process

境内外授权及公证 (境内委托境外的不需要办理授权及公证)
Authorize and notarize domestic and foreign entities
(authorization and notarization are not required for overseas authorization by domestic entities)

首次备案
File for the first time

账户申请
Apply for account

确定配方、标签
Confirm formulas and labels

样品检测
Test samples

整理其他资料
Organize other documents

提交备案资料至 NMPA 信息服务平台
Submit filing documents to the NMPA Information Service Platform

NMPA 资料整理
Documents organized by NMPA

完成备案
Complete filing

每年向承担备案的药监部门报告进口情况，以及符合法律法规、强制性国家标准、技术规范的情况
Report import status to the competent drug regulatory department annually, as well as compliance with laws, regulations, mandatory national standards, and technical specifications.

进口特殊化妆品注册流程

Imported Special Cosmetics Registration Process

境内外授权及公证 (境内委托境外的不需要办理授权及公证)
Authorize and notarize domestic and foreign entities
(authorization and notarization are not required for overseas authorization by domestic entities)

首次申报
Declare for the first time

账户申请
Apply for account

确定配方、标签
Confirm formulas and labels

样品检测
Test samples

整理其他资料
Organize other documents

提交 NMPA
Submit to NMPA

形式审查 (决定是否受理)
Formally review
(decide whether to accept)

评审中心技术评审 (专家审核)
Technical review by the Evaluation Center
(expert review)

行政审批 (决定是否批准)
Administratively approve
(decide whether to approve)

核发注册证
Issue registration certificate

进口化妆品所需文件
DOCUMENTS REQUIRED FOR IMPORTED COSMETICS

账户注册所需资料
Documents Required for Account Registration

1. 注册人 / 备案人信息表及质量安全负责人简历；
Information sheet(s) of the registrant or the filing person, and resume of the person responsible for quality and safety;

2. 注册人 / 备案人质量管理体系概述；
Overview of the Quality Management System by the registrant or the filing person;

3. 注册人 / 备案人不良反应监测和评价体系概述；
Overview of the adverse reaction monitoring and evaluation system by the registrant or filing person;

4. 境外注册人 / 备案人应当提交境内责任人信息表；
Information sheet(s) of the local person responsible;

5. 境内责任人授权书原件及其公证书原件；
Original authorization letter and its notarization certificate of the domestic responsible person;

6. 注册人 / 备案人有自行生产或者委托境外生产企业生产的，应当提交生产企业信息表和质量安全负责人信息，一次性填报已有生产企业及其信息。生产企业为境外的，应当提交境外生产规范证明资料原件；
If the registrant or the filing person produces independently or entrusts overseas enterprises for production, the information sheet(s) of production enterprises and the details of the person responsible for quality and safety shall be submitted, along with a one-time report of existing production enterprises and their information. If the production enterprise is overseas, the original proof of compliance with overseas manufacturing standards shall be submitted;

7. 其他相关资料。
Other relevant documents.

产品注册备案申报所需要资料

Documents Required for Product Registration & Filing

1. 《化妆品注册备案信息表》及相关资料 (含境外已上市销售证明文件)；

   Registration and Filing Information Form for Cosmetics and related documents (including proof of overseas market sales certificate);

2. 产品名称信息 (含商标注册证明等)；

   Product name information (including trademark registration certificate, etc.);

3. 产品配方 (包括原料序号、原料名称、百分比含量、使用目的、原料安全信息)；

   Product formula (including ingredient serial number, ingredient name, percentage content, intended use, and ingredient safety information);

4. 产品执行的标准；

   Product standards;

5. 产品标签样稿、境外生产国 (地区) 产品的销售包装；

   Drafts of product labels and sales packaging from the country (or region) where the product is manufactured overseas;

6. 产品检验报告 (包括微生物和理化检验、毒理学试验、人体安全性试验和人体功效试验报告等)；

   Product test reports (including microbiological and physicochemical tests, toxicology tests, human safety tests, and human efficacy testing report, etc.);

7. 产品安全评估资料；

   Product safety assessment documents;

8. 可能有助于备案的其他资料。所有资料都必须提供中文简体版。

   Other materials that may assist in the filing. All documents must be provided in Simplified Chinese.

备注 Remarks:

- 普通化妆品每年向承担备案管理工作的药品监督管理部门报告进口情况，以及符合法律法规、强制性国家标准，技术规范的情况。

  The import status of general cosmetics, as well as the compliance with laws regulations, mandatory national standards, and technical specifications need to be reported to the drug regulatory authorities responsible for filing management annually.

- 特殊化妆品注册证有效期为 5 年，持有人须在注册证到期前 90 个工作日至 30 个工作日期间提出延续注册申请。过期自动作废，必须重新申请。

  The validity period of the special cosmetics registration certificate is 5 years. The holder must submit an application for renewal within 90 to 30 working days before the expiration of the registration certificate. If expired, the certificate will be automatically invalidated and a new application must be submitted.

周期（含检测时间）
TIMELINE (INCLUDING TESTING TIME)

进口普通化妆品
Imported General Cosmetics

2.5–6 个月

2.5–6 months

进口特殊化妆品
Imported Special Cosmetics

6–22 个月
(根据具体产品功效类型而定)

6–22 months (depends on the specific product's efficacy type)

化妆品测试需要提供的样品数量
QUANTITY OF SAMPLES REQUIRED FOR COSMETICS TESTS

样品独立包装净含量 Net Content of Individually Packaged Sample	＞10g (ml)	＜10g (ml)
常规备案检测量 Test Quantity for Regular Filing	6 件 6 Items	总量不少于 80g (ml) Total Amount Not Less Than 80g (ml)
皮肤光毒性试验 Skin Phototoxicity Test	总量不少于 100g (ml) Total Amount Not Less Than 100g (ml)	
急性眼刺激性 / 腐蚀性试验 Acute Eye Irritation / Corrosion Test	总量不少于 100g (ml) Total Amount Not Less Than 100g (ml)	
皮肤变态反应试验 Skin Sensitization Reaction Test	总量不少于 200g (ml) Total Amount Not Less Than 200g (ml)	
皮肤刺激性 / 腐蚀性试验 Skin Irritation / Corrosion Test	总量不少于 200g (ml) Total Amount Not Less Than 200g (ml)	
体外哺乳动物细胞染色体畸变试验 in Vitro Mammalian Cell Chromosome Aberration Test	总量不少于 100g (ml) Total Amount Not Less Than 100g (ml)	
体外哺乳动物细胞基因突变试验 in Vitro Mammalian Cell Gene Mutation Test	总量不少于 100g (ml) Total Amount Not Less Than 100g (ml)	

备注 Remarks:

- 针对样品送检量问题，申请减少送检样品量时，请先与销售工程师确认；
  When applying to reduce the amount of samples for testing, please confirm with the sales engineer first;
- 企业应当一次性提供检测所需足量、包装完整、同一名称、同一生产日期 / 批号、同一规格的样品；
  Enterprises should provide an adequate amount of samples required for testing at one time, with complete packaging, identical product name, production date / batch number, and specifications;
- 提供的样品包装为市售 (销售) 包装，包装上标识完整，内容与申请单一致；
  The provided samples should be in commercial packaging, with complete labeling matching the contents of the application form;
- 以上样品量为单个项目常规用量，如有加测项目需再与销售工程师确认送检样品量。
  The above–mentioned sample quantities are the regular amount for one single testing item. For additional testing items, please reconfirm the sample quantities with the sales engineer.

一站式服务
ONE–STOP SERVICE

测试服务 Testing Services

- 重金属测试 Heavy Metals Test
- 微生物测试 Microbiological Examination
- 防腐剂挑战测试 Preservative Challenge Test
- 风险物质测试 Hazardous Substance Test
- 毒理学测试 Toxicology Test

文件服务 Document Services

- 安全评估报告 Safety Assessment Report
- 标签成分审核 Label & Ingredient Review
- 文件翻译 Document Translation
- 辅助准备注册备案其他所需资料
  Assistance in Preparing Other Required Documents for Registration & Filing

环球网络 STC Global Network

如欲了解更多相关信息，请与我们联系：
Find out more, contact us now.

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