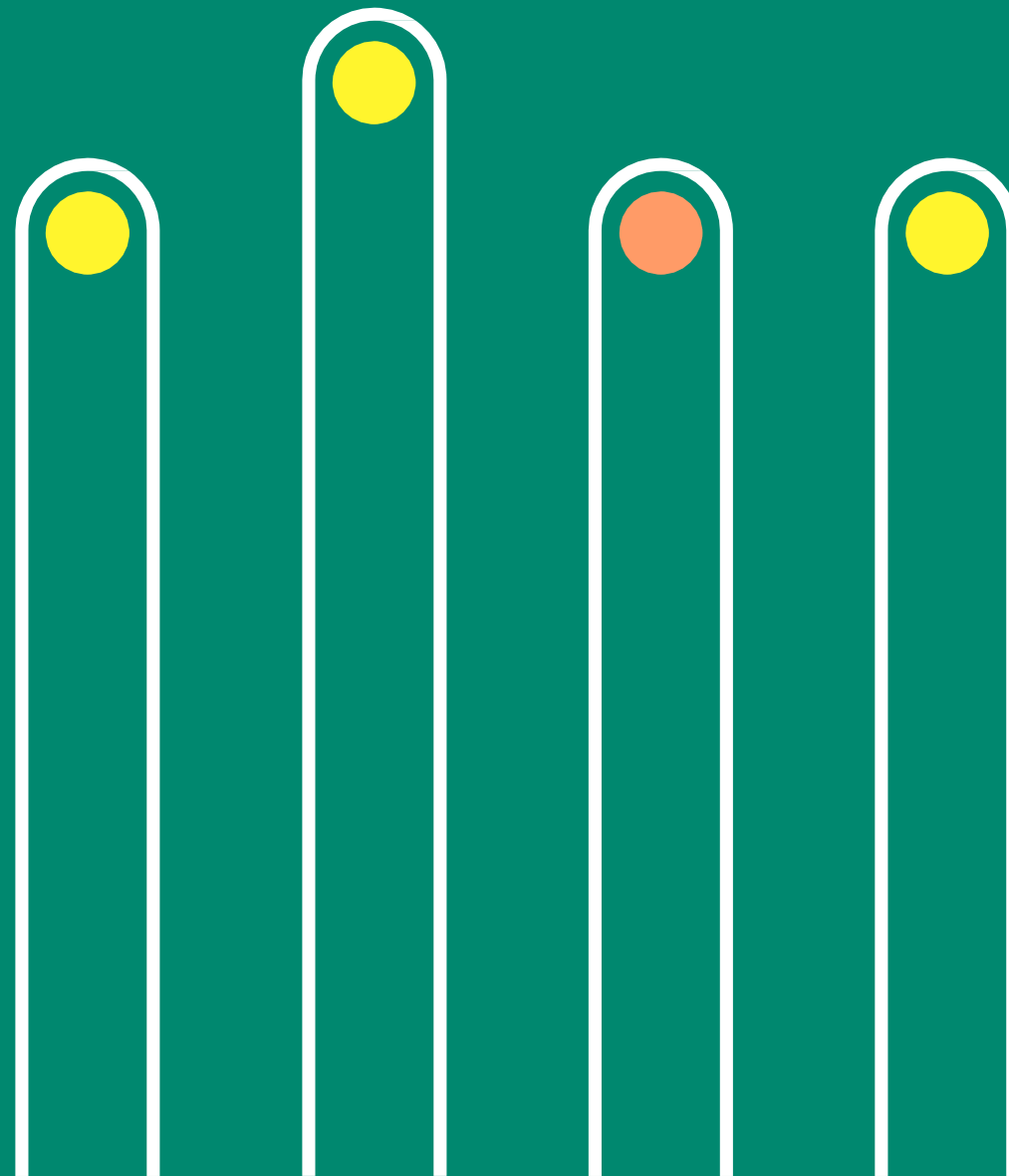




# 法规支持网站说明

变更控制通知支持及法规支持文件

[cytivalifesciences.com.cn/rsf](http://cytivalifesciences.com.cn/rsf)  
2021年2月12日



# 登录网站

转到 [cytivalifesciences.com.cn/rsf](https://cytivalifesciences.com.cn/rsf)

单击获得法规支持

## 监管支持

为在监管环境中使用的产品提供变更控制通知和文件

获取监管支持

### 无需订阅，即可下载

声明  
ISO 证书  
符合性声明和 EC 证书 (Eysins 厂区)  
产品证书  
关于 CCN 服务的传单  
REACH

### 资源

监管支持文档  
提取物信息  
变更控制通知  
质量管理  
安全供货/业务连续性管理  
可持续性  
EHS 计划

### 支持门户帮助

视频教程  
使用说明  
了解新功能  
常见问题解答  
电子邮件通知 - 该做什么

# 登录网站

如果您已经拥有帐户，请使用您的电子邮件地址和密码登录。

如果您还没有帐户，请单击**立即注册**，然后按照说明创建帐户。

请记得使用您的公司电子邮件地址进行注册。

在订阅变更控制通知 (CCN) 时考虑使用共享收件箱，以尽量减少人员变动可能引起的沟通不畅。



## 登录

用户名

密码

显示 

登录

[忘记密码?](#)

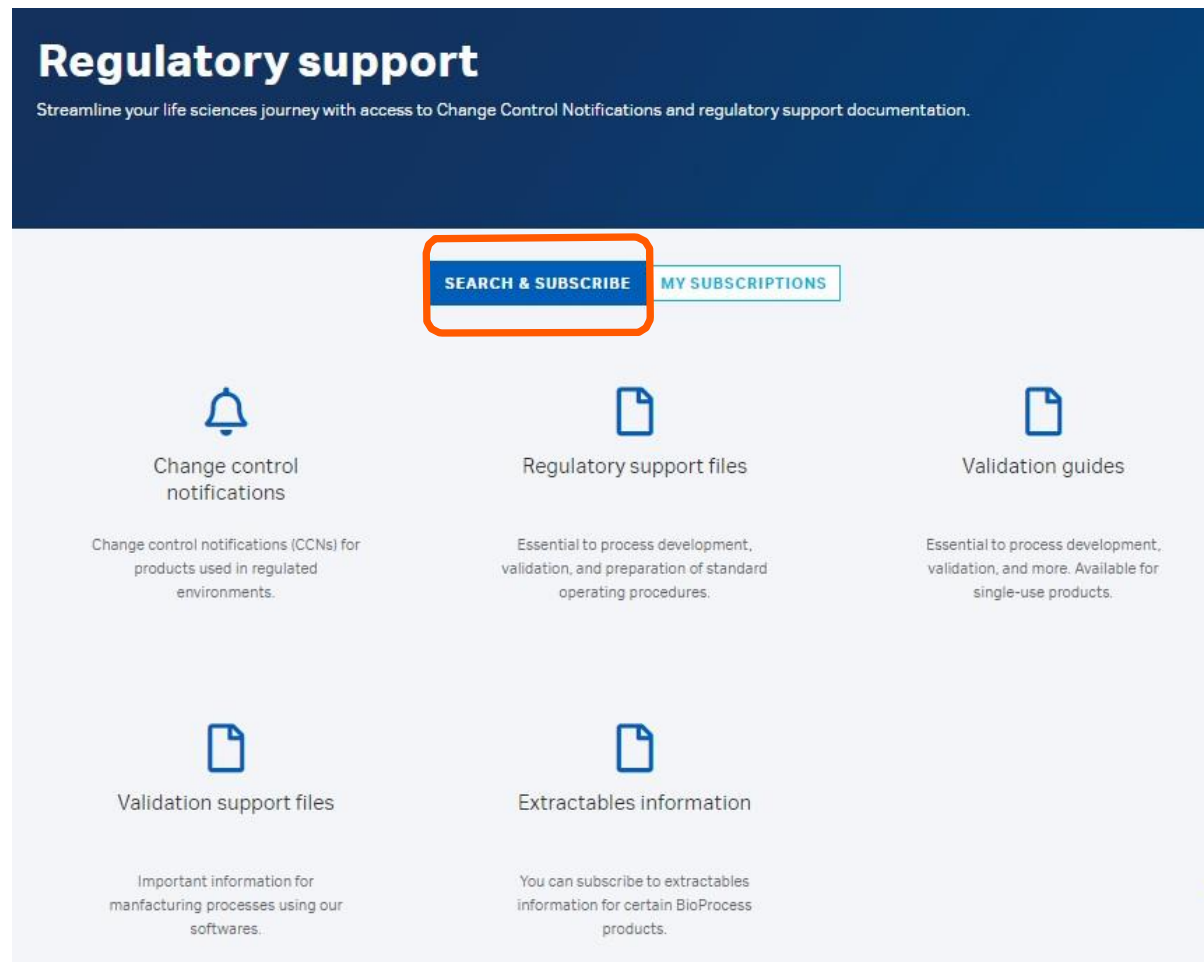
还没有在我们这里注册吗?

立即注册

# 开始订阅

登录后，将为您重定向至法规支持网站的**搜索和订阅(Search & Subscribe)**界面。


单击方框选择您想订阅的文档类型。




# 订阅变更控制通知

按照在线说明搜索产品。

[SEARCH & SUBSCRIBE](#) [MY SUBSCRIPTIONS](#)

[<](#)  **Change control notifications**  
Search by product code or product name. See examples below.

Search for custom products. Tick the box and search by complete product code only. For custom HyClone products, please contact [Hyclone.Changenotice@cytiva.com](mailto:Hyclone.Changenotice@cytiva.com).

 Are you looking for spare parts or software? [Subscribe here.](#)

# 订阅变更控制通知

搜索产品代码（如888-0070-C）  
以生成搜索结果列表。

单击**订阅 (Subscribe)** 即可订阅搜索结果中的产品。

The screenshot shows a web interface for managing subscriptions. At the top, there are two buttons: "SEARCH & SUBSCRIBE" (highlighted in blue) and "MY SUBSCRIPTIONS". Below this is a section titled "Change control notifications" with a back arrow and a bell icon. The text below the title says "Search by product code or product name. See examples below." A search bar contains the text "888-0070-C". Below the search bar, there is a checkbox labeled "Search for custom products. Tick the box and search by complete product code only. For custom HyClone products, please contact Hyclone.Changenotice@cytiva.com." Below this is a promotional message: "+ Are you looking for bioprocess spare parts or software? Subscribe here. Select a product area below to be notified of changes regarding spare parts or software." At the bottom, it says "Showing results 1 - 3 of 3". A table lists one product: "888-0070-C XDR-500 Pro Bag". To the right of the table is a green "Subscribe" button.

SEARCH & SUBSCRIBE MY SUBSCRIPTIONS

< Change control notifications  
Search by product code or product name. See examples below.

888-0070-C

Search for custom products. Tick the box and search by complete product code only. For custom HyClone products, please contact Hyclone.Changenotice@cytiva.com.

+ Are you looking for bioprocess spare parts or software? Subscribe here.  
Select a product area below to be notified of changes regarding spare parts or software.

Showing results 1 - 3 of 3

888-0070-C	XDR-500 Pro Bag	<b>Subscribe</b>
------------	-----------------	------------------

# 订阅变更控制通知

选择一个产品区域即可订阅备件和软件的变更控制通知。

SEARCH & SUBSCRIBE MY SUBSCRIPTIONS

< Change control notifications  
Search by product code or product name. See examples below.

search for e.g. MabSelect, CB0010L11-11, 17051005, RTPUFP-300-E-65S, 888-0070-C, SH31039.02

Search for custom products. Tick the box and search by complete product code only. For custom HyClone products, please contact Hyclone.Changenotice@cytiva.com.

+ Are you looking for spare parts or software? Subscribe here.

- Are you looking for bioprocess spare parts or software? Subscribe here.  
Select a product area below to be notified of changes regarding spare parts or software.

Amersham ImageQuant [Subscribe](#)

AxiChrom columns [Subscribe](#)


# 订阅变更控制通知

要搜索定制产品，请勾选标记为红色的方框。

请注意，订阅定制产品的变更控制通知需要输入完整的产品代码（即不提供部分搜索结果。）

本网站现已提供定制 HyClone 产品的变更控制通知，但您需要联系 [Hyclone.Changenotice@cytiva.com](mailto:Hyclone.Changenotice@cytiva.com) 开启订阅。

SEARCH & SUBSCRIBE MY SUBSCRIPTIONS

<  Change control notifications  
Search by product code or product name. See examples below.

search for e.g. MabSelect, CB0010L11-11, 17051005, RTPUFP-300-E-65S, 888-0070-C, SH31039.02

Search for custom products. Tick the box and search by complete product code only. For custom HyClone products, please contact Hyclone.Changenotice@cytiva.com.

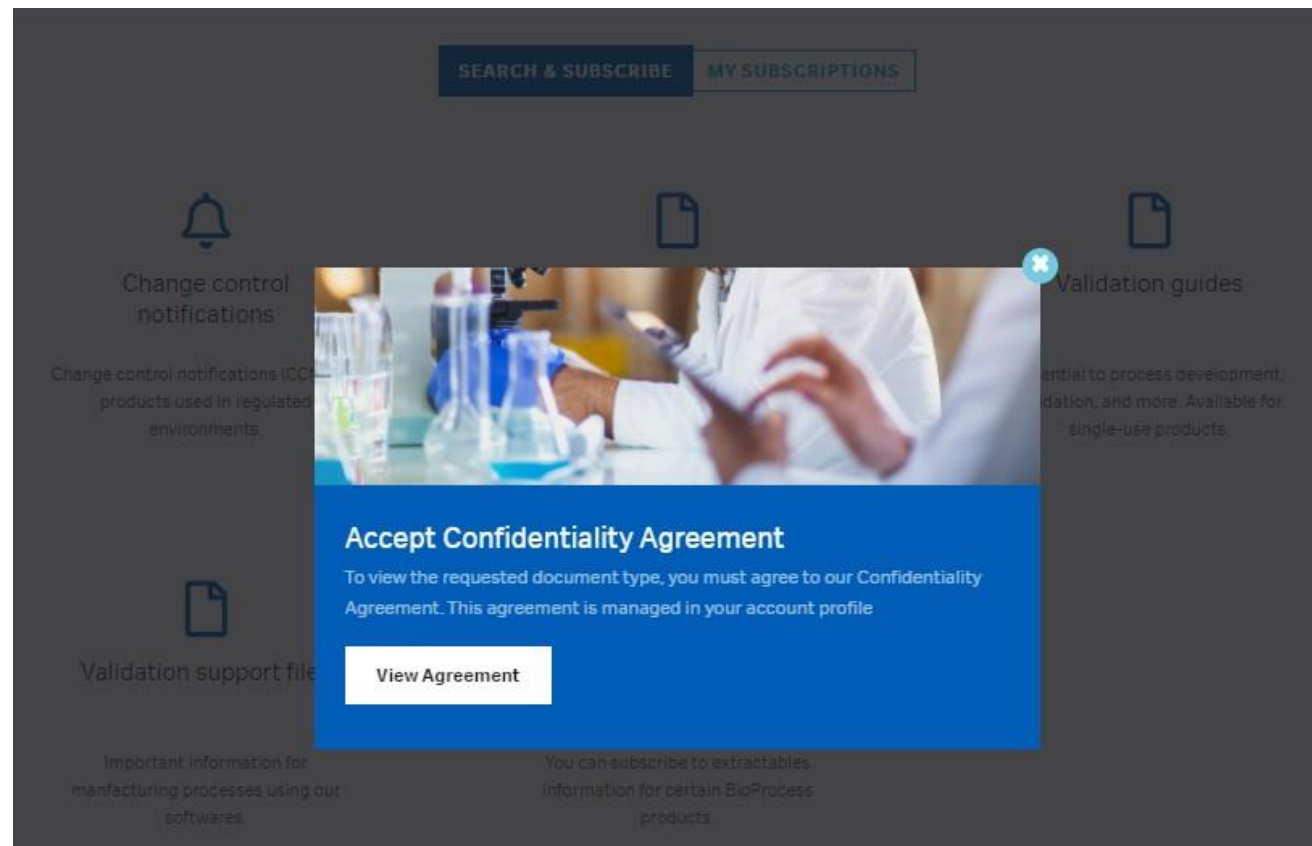
+ Are you looking for spare parts or software? Subscribe here.



# 保密协议

您首次请求订阅法规支持文件时，系统会提示您接受我们的保密协议。请注意，变更控制通知不要求签署保密协议。

要查看并接受保密协议，请单击**查看协议 (View Agreement)**。



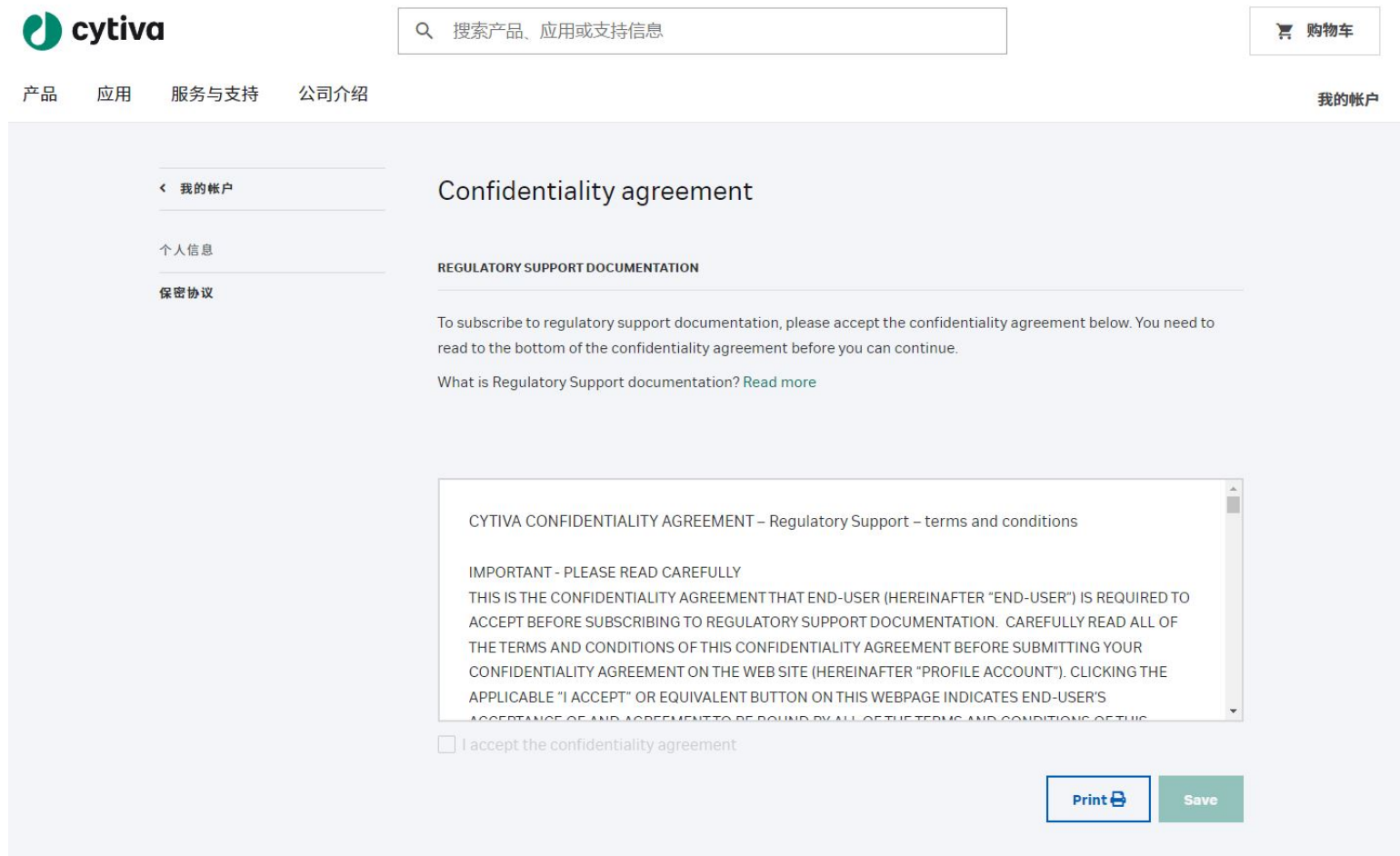
# 保密协议

10

勾选您接受保密协议，然后单击**保存(Save)**。

该协议有效期为一年。一年后，您将收到一封通知续签协议的电子邮件。您登录 Cytiva 时，系统还会提示您在线续签协议。

您的协议到期时，您仍会收到监管支持文件订阅的通知。但您在线续签协议之前，您将无法访问这些文件。



The screenshot shows the Cytiva website interface. At the top, there is a search bar with the text "搜索产品、应用或支持信息" and a shopping cart icon labeled "购物车". Below the search bar, there are navigation links: "产品", "应用", "服务与支持", and "公司介绍". On the right side, there is a link for "我的帐户".

The main content area is titled "Confidentiality agreement". Below the title, there is a section for "REGULATORY SUPPORT DOCUMENTATION". The text reads: "To subscribe to regulatory support documentation, please accept the confidentiality agreement below. You need to read to the bottom of the confidentiality agreement before you can continue." There is a link "What is Regulatory Support documentation? Read more".

A scrollable box contains the following text: "CYTIVA CONFIDENTIALITY AGREEMENT – Regulatory Support – terms and conditions". Below this, it says "IMPORTANT - PLEASE READ CAREFULLY" and "THIS IS THE CONFIDENTIALITY AGREEMENT THAT END-USER (HEREINAFTER 'END-USER') IS REQUIRED TO ACCEPT BEFORE SUBSCRIBING TO REGULATORY SUPPORT DOCUMENTATION. CAREFULLY READ ALL OF THE TERMS AND CONDITIONS OF THIS CONFIDENTIALITY AGREEMENT BEFORE SUBMITTING YOUR CONFIDENTIALITY AGREEMENT ON THE WEB SITE (HEREINAFTER 'PROFILE ACCOUNT'). CLICKING THE APPLICABLE 'I ACCEPT' OR EQUIVALENT BUTTON ON THIS WEBPAGE INDICATES END-USER'S ACCEPTANCE OF AND AGREEMENT TO BE BOUND BY ALL OF THE TERMS AND CONDITIONS OF THE".

At the bottom of the scrollable box, there is a checkbox labeled "I accept the confidentiality agreement". Below the checkbox, there are two buttons: "Print" and "Save".

10

# 文件法规支持文档

## 法规支持文件

搜索产品代码或产品名称以开始  
订阅。

## 验证指南、验证支持文件和 可溶出物信息

从列出的选项中选择订阅  
这些文件。



### Regulatory support files

Search by product code or product name.



search for e.g. MabSelect, 17051005



### Validation guides

Select from the list below.

Showing results 1 - 15 of 31

VG ReadyCircuit Assemblies China

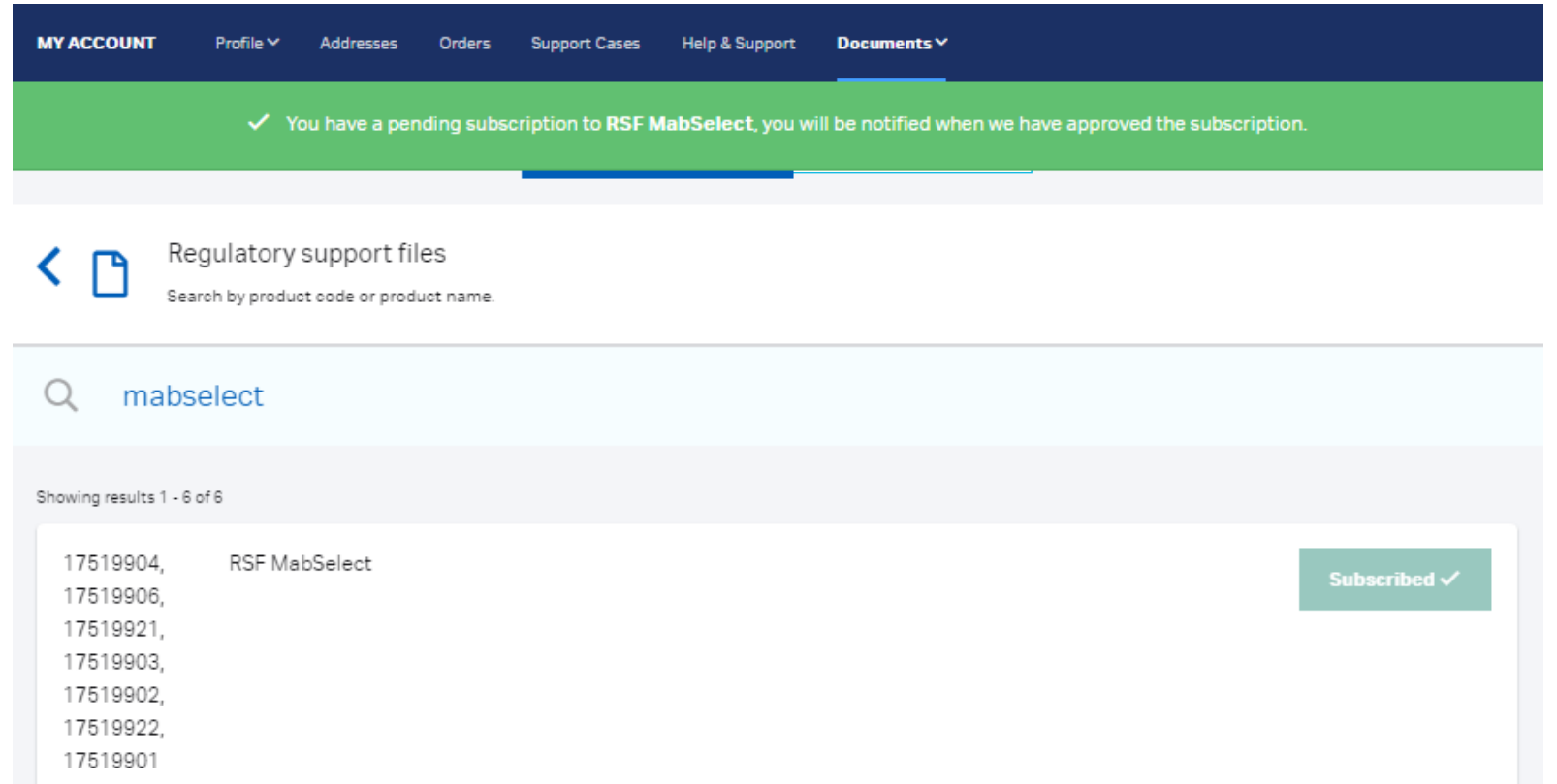
Subscribe

# 订阅法规支持文件

您首次订阅法规支持文件时，我们的支持团队会审批您的请求。此过程通常需要两个工作日完成。

您的请求在审核中时，您会收到一条在线通知；请求通过时，您会收到电子邮件通知。审核通过后，您将能够立即订阅大部分法规支持文件。

**注意：**由于某些订阅可能包含敏感信息，因此会有额外的审批步骤。如果您的请求需要经过额外审批，您将收到在线通知。该步骤同样由我们的支持团队完成，您的请求一经批准，您就会收到电子邮件通知。



The screenshot shows a user account interface with a dark blue header containing navigation links: MY ACCOUNT, Profile, Addresses, Orders, Support Cases, Help & Support, and Documents. A green banner below the header displays a confirmation message: "You have a pending subscription to RSF MabSelect, you will be notified when we have approved the subscription." Below this, a section titled "Regulatory support files" includes a search bar with the text "mabselect" and a search icon. The search results show a list of product codes: 17519904, 17519906, 17519921, 17519903, 17519902, 17519922, and 17519901, all associated with "RSF MabSelect". A green "Subscribed" button with a checkmark is visible on the right side of the results list.






# 查看您的有效订阅

转到**我的订阅(My Subscriptions)**，选择您想查看的订阅文件类型。

在此页面您还可以导出所有当前订阅文件的列表。

SEARCH & SUBSCRIBE MY SUBSCRIPTIONS

Export a list of all current subscriptions

-   
Change control notifications  
Change control notifications (CCNs) for products used in regulated environments.
-   
Regulatory support files  
Essential to process development, validation, and preparation of standard operating procedures.
-   
Validation guides  
Essential to process development, validation, and more. Available for single-use products.
-   
Validation support files  
Important information for manufacturing processes using our softwares.
-   
Extractables information  
You can subscribe to extractables information for certain BioProcess products.

# 电子邮件通知

## 变更控制通知

当您订阅的变更控制通知发布新内容时，您将收到一封电子邮件，即变更控制通知包括多个产品。每封电子邮件都会列出您订阅的所有受影响产品。

## 法规支持文件

当您订阅的文件更新时，您将收到电子邮件通知。



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BioProcess、Hyclone 和 MabSelect 是 Global Life Sciences Solutions USA LLC 或以 Cytiva 作为经营别称的关联公司的商标。

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