



Price list 价目表

证书原件费用

Certificates Our fees

证书	费用	Certificate	Fees
Ia. 在首次或换发证书过程 如下语言中的2种：英文、德文或中文 如下语言中的3种：英文、德文或中文	免费 € 60,-	2 certificates issued after finalising the initial or re-certification process in 2 of the following languages respectively: English, German or Chinese in 3 of the following languages respectively: English, German and Chinese	free of charge € 60,-
Ib. 英文、德文或中文之外的语言	€ 120,- / 张	Certificate in language different than English, German or Chinese	€ 120,- / piece
Ic. 如需特殊文字的证书（如 俄文）	依据报价	Certificate in language, which requires different font (e.g. Russian)	according to quotation
Id. 额外的 DIN A4 证书原件 10 张以内，每种语言	€ 15,- / 张	Additional DIN A4 certificates up to 10 pieces, each variant	€ 15,- / piece
Ie. 额外的 DIN A4 证书原件 20 张以内，每种语言	€ 10,- / 张	Additional DIN A4 certificates up to 20 pieces, each variant	€ 10,- / piece
If. 额外的 DIN A4 证书原件 30 张以内，每种语言	€ 8,- / 张	Additional DIN A4 certificates up to 30 pieces, each variant	€ 8,- / piece
Ig. 额外的 DIN A4 证书原件 30 张以上，每种语言	依据报价	Additional DIN A4 certificates more than 30 pieces, each variant	according to quotation
Ih. DIN A3 格式证书，每种语言	€ 25,- / 张	Certificate DIN A3 format, each variant	€ 25,- / piece
Ii. 不同版本格式的有效证书(每种语言，每种版本)	€ 60,- / 张	Different versions of valid certificates (per language, each version)	€ 60,- / piece

证书或产品规格的改变

Change of certificates or of main product specifications

服务	费用	Service	Fees
<p>2a. 变更通知</p> <ul style="list-style-type: none"> 证书变更 如 因增加产品和或活动引起的范围扩展，地址变更，法律实体变更 涉及新证书 	根据实际发生费用 至少 € 250,-	Change Notification <ul style="list-style-type: none"> Change of certificates as for example extension of scope due to additional products and/or activities, change of address, change of legal entity – incl. new certificate 	according to expenses min. € 250,-
<p>2b.</p> <ul style="list-style-type: none"> 产品规格变更或不影响证书的生产过程，如原材料、包装、灭菌、使用说明、增加供应商等变更 涉及确认信 		<ul style="list-style-type: none"> Changes of main product specifications or manufacturing processes which not affect the scope of the certificate as changes of material, packaging, sterilization, instructions for use, additional suppliers – incl. confirmation letter 	

证书使用

证书允许完整版发布或将完整版复印件发给第三方；
证书允许放大或缩小，但应以1:1比例清晰可辨识的复印；
证书不允许修改、伪造或提取（包括部分放大）。

Use of certificates

Certificates may be published as a whole or passed on to third parties as copies. Enlargements and reductions to scale are possible. Certificate copies in 1:1 scale are to be clearly identified as such. Amendments, falsification and extracts (including enlargements in parts) of certificates are not allowed.

收费基数

Rates and fees

	服务	费用	Service	Fees
3a.	体系认证每小时工作 (IIb及以下医疗产品)	€ 120,- / 小时	Rate per working hour QM Certification (up to class IIb medical devices)	€ 120,- / hour
3b.	体系认证每小时工作 (III类医疗产品)	€ 163,- / 小时	Rate per working hour QM Certification (class III medical devices)	€ 163,- / hour
3c.	IIb 类和或以下产品技术文件评审	€ 120,- / 小时	Technical File Review (up to class IIb medical devices)	€ 120,- / hour
3d.	产品认证评估 (仅针对III类产品认证)	€ 175,- / 小时	Product certification (for class III medical device certification only)	€ 175,- / hour
3e.	客户维护	€ 120,- / 年	Customer service	€ 120,- / year
3f.	评审委员会每小时工作	€ 163,- / 小时	Rate per working hour Certification Body	€ 163,- / hour
3g.	不通告审核 至少	根据实际发生费用 € 3.550,-	Unannounced Audit	according to expenses min. € 3.550,-

收费基数

Rates and fees

服务	费用	Service	Fees
4a. 差旅费用 (酒店, 机票等)	根据实际发生费用	Travel expenses (hotel, flight ticket, etc.)	according to expenses
4b. 旅行时间费用	每位德国审核员/专家 每位中国审核员/专家	Travel time	per German auditor / expert per Chinese auditor / expert
4c. MDD93/42/EEC 的证书费	€ 936,- € 468,-	License fee for certificates according to Directive 93/42/EEC (per procedure)	€ 936,- € 468,-
4d. ISO 13485 证书费	€ 770,- / 年	License fee for certificates according to ISO 13485	€ 770,- / year
	€ 510,- / 年	License fee for certificates according to ISO 13485	€ 510,- / year

您是否已成功获得认证?
贵司准备分享这一认证成果了吗?

我们准备了一些用于宣传的认证标识和印章,
详见我们的<认证标识使用和认证印章>指南。



Have you been successfully certified?
Congratulations!

Would you like to share your achievement with others?
We have prepared some promotional material for you.
For details please see our guide "Promotional products & certification seal".



其它费用

Other service fees

服务	费用	Service	Fees
5a. 事故报告(成立报告措施采取等) 根据实际发生费用	根据实际发生费用 € 163,- / 小时	Incidents reporting (opening an incident case, proceeding of taken measures, etc.)	according to expenses with 163,-€ / hour
5b. 确认信函 ■ 针对产品 ■ 其它	€ 250,- € 125,-	Confirmation letter ■ for products ■ other	€ 250,- € 125,-
5c. 使馆认证(2张证书)服务费	€ 200,- 追加公认证实际产生费用	Notarization (incl. 2 certificates)	€ 200,- plus notary and authority fees
5d. 当次追加使馆认证费	€ 20,- / 张 追加公认证实际产生费用	Further notarisations of certificates	€ 20,- / piece plus notary and authority fees
5e. 过渡证书(根据客户需求)	至少 € 250,-	Transition certificates (at customer's request)	min. € 250,-
5f. 快递服务(文件寄送)	€ 50,-	Courier service (sending of documents)	€ 50,-

GERMANY Headquarters

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关于此价格表

- * 自 2019.01.15 生效日起有效
- * MEDCERT 的 „General Order and Payment Conditions“ 同时更新
- * 此价格目录将替代以前的版本。

About this price list

- * Valid from January 15, 2019.
- * The „General Order and Payment Conditions“ of MEDCERT GmbH are effective per the current revision.
- * With the publication of this price list all previous price lists become invalid.