



DEKRA Certification UK Ltd

2928:3 Medical Device Services and Fees

Contract Fees

| | | | |
|---|--------------------------|-------|-------|
| New Customer Application Fee | per application | £500 | €580 |
| ISO-certificate(s) | per certificate per year | £1000 | €1160 |
| UKCA-certificate (first) | per certificate per year | £1500 | €1745 |
| Additional certificate (= every next certificate, renewal, major scope change*) | per certificate per year | £1000 | €1160 |

Standard Service Delivery Fees

| | | | |
|--|--------------|-------|-------|
| Standard Application Review (New standalone submission) | per instance | £1500 | €1745 |
| Application Review UKCA Abridged or UKCA+ | per instance | £4800 | €5580 |
| QMS Audit (excluding travel and expenses) | per hour | £325 | €375 |
| Technical Documentation Review Fees (including Notice of Change) | per hour | £380 | €440 |
| Extended Project Management Service | Per Year | £2800 | €3260 |

DEKRA Certification UK Ltd

Stokenchurch House, Oxford Road, Stokenchurch, Bucks, ENGLAND, HP14 3SX

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Company Registration Number 13129030



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Variable Review and Audit Fees

| | | | |
|---|-----------------|----------------|---------|
| Review of Corrective Actions, Review of Vigilance Notifications, Review of Periodic Safety Update Reports etc. | per hour | £380 | €440 |
| Additional audits (e.g. Corrective Action audits, Short Notice audits following an incident, Supplier and Subcontractor Audits) (1 auditor) | per half day | £1500 | €1745 |
| External consultations, including translation, clinical and expert consultations | per event | at cost | At cost |
| Unannounced Audit* (2 auditors) | per audit day | £6500 | €770 |
| Travel time | per hour | £150 | €175 |
| Travel, lodging and subsistence expenses | per audit event | billed at cost | At Cost |

Notes:

* Minor scope changes and clarifications identified by DEKRA may not incur charge

These fees are for guidance only and may vary slightly due to currencies and different travel policies that may apply to some specific geographies. All prices were determined using the GBP to EUR exchange rate at the time of publishing please be aware fluctuations in the exchange rate may affect the final cost price.

All prices exclusive of VAT where applicable

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