bsi.

Medical Devices

BSI Work Authorisation Form (GBP)

Effective 1 January 2018

Please complete the following items and select the service required on pages 2-4:

Company name:	Viamed Ltd
Contact name:	Derek Lamb
Current certificate number(s):	Quality Assurance: MD 78787 Design Examination(s):
Product name/description:	
Provisional updated scope(s):	Quality Assurance: The design, manufacture and service of: oxygen sensors and accessories, Peripheral Nerve Stimulators, Simulation Equipment, Infant T-piece resuscitators, Apgar timer. Distribution and service of electromedical devices. Design Examination(s):

Medical Device Reviews

The amount of time involved in these reviews is dependent on a number of critical factors:

- The quality and completeness of the submission
- Whether the device is novel and/or high risk
- Level of review required

Design Dossier Reviews

☐ ***New Submission*** ☐ ***Supplement / Change***

Review service requested:

Design Dossier Review (Standard Service):

☐ **CE-Standard (£2,620 per day)**

Design Dossier Review (FastTrack Services):

☐ **CE-FastTrack (£6,560 per day)**

☐ **CE-Dedicated (£6,950 per day)**

☐ **CE-Onsite (£7,730 per day)**
(Exclusive of travel time and expenses)

All Design Dossiers that are recommended to the BSI Certification Panel for CE Marking certification will be charged a Certification Panel review fee of 10% of the total review cost (up to maximum £3,640).

Certain aspects of technical documentation reviews require BSI to utilize external expert guidance/services to satisfy the Directive(s) (£3,640 per day).

Animal tissue and medicinal review fees are in addition to the design dossier review fees.

The review fees do not include required consultation fees with Medicines Competent Authorities or the European Medicines Agency (EMA).

For device drug combination reviews, administration and processing fee applies for Competent Authority consultations (£270).

For IVD Annex II List A products, fees exclude verification of manufactured product fees.

Techncial File Audits (excluding surveillance audits)

☐ ***New Submission*** ☐ ***Supplement / Change***

Review service requested:

Technical File Audit (Standard Service):

☐ **CE-Standard - desktop (£2,060 per day)**

Technical File Audit (FastTrack Services):

☐ **CE-FastTrack (£5,160 per day)**

☐ **CE-Dedicated (£5,570 per day)**

☐ **CE-Onsite (£6,190 per day)**
(Exclusive of travel time and expenses)

Certain aspects of technical documentation reviews require BSI to utilize external expert guidance/services to satisfy the Directive(s) (£3,640 per day).

Summary Technical Report (STR)

Review service requested:

☐ **CE-Standard (£2,620 per STR)** ☐ **CE-FastTrack (£6,560 per STR)**

CE Certificate Renewals

Certificates for CE Marking are issued for 5 years and require a renewal process to be completed prior to the expiration date of the certificate. Manufacturers are responsible for requesting renewal and will be required to provide supporting documentation.
If BSI receives the submission for renewal less than 6 months from certificate expiry, we cannot ensure that the certificate will not expire before the renewal process is completed. In this case, products will not be covered by a valid EC Certificate during the time between certificate expiry and renewal. In addition, full documentation received with less than 6 months to expiry of the certificate will be charged at the dedicated rate.

EC Design Dossier Examination Certificates:

Review service requested:

☐ **Renewal CE-Standard (£2,620 per day)**

☐ **Renewal CE-FastTrack (£6,560 per day)**

☐ **Renewal CE-Dedicated (£6,950 per day)**

EC Quality Assurance Certificates:

Review service requested:

☐ **Renewal CE-Standard (£2,060 per day)**

☐ **Renewal CE-FastTrack (£5,160 per day)**

☐ **Renewal CE-Dedicated (£5,570 per day)**

EC Quality Assurance Certificate renewal fees are based on a minimum 1 day review (per Quality Assurance certificate).

EC Design Dossier Examination Certificate renewal fees are based on a minimum 2 day review (per Design Examination certificate).

Fees are based on the assumption that complete and largely satisfactory documentation is submitted to BSI. Additional fees will be charged if the documentation is not satisfactory and additional review time is required.

Animal tissue and medicinal review fees are in addition to the EC Design Dossier Examination Certificate renewal fees (estimated additional 0.5 day review for each).

ISO 13485 Certificate Renewals

Certificates for ISO 13485 are issued for 3 years and require a renewal process to be completed prior to the expiration date of the certificate. Manufacturers are responsible for requesting renewal and will be required to provide supporting documentation.

ISO 13485:

☒ **ISO 13485 (£650 per certificate)**

Administration Fees

☐ **Certificate changes/re-issue fee (£520)**
Certificate changes /re-issue fee is based on a minimum of 2 hours of work. Additional fees will be charged for work taken over 2 hours (£260 per hour rate).

☐ **Regulatory confirmation (Taiwan/Ukraine Letters) (£1,200)**

☐ **Regulatory confirmation (Standard Letter) (£390)**
Regulatory confirmation (standard letter) fee is based on a minimum of 1.5 hours of work. Additional fees will be charged for work taken over 1.5 hours (£260 per hour rate).

Travel Fees

Travel time is charged at £160 per hour for onsite audits (the first hour each way of travel time is non-chargeable). The maximum chargeable travel time is 8 hours in one given day. For exclusive day rates, expenses are at cost (airfare, accommodation, meals, car rental as applicable).

Notes

- The applicant herewith declares to have lodged no application with any other notified body for the same products and conformity assessment procedure.
- The time and cost provided for the technical documentation review is an estimated range based on our experience with similar submissions. The costs associated with the review will be impacted by the volume, complexity, completeness and quality of the submitted file.
- Fees quoted are based on the assumption that complete and largely satisfactory technical documentation is submitted to BSI. Additional fees will be charged if the technical documentation is not satisfactory and/or non-conformities are raised and additional review time is required.
- FastTrack Programs for technical documentation review service is subject to availability. BSI reserves the right to refuse FastTrack Program service for any reason. None of BSI's standard and Fast-Track review programs represent a guarantee that BSI will achieve the selected timeline under every set of circumstances. BSI cannot be held responsible for missing a selected timeline, will not reimburse customer for missing a selected timeline, nor is BSI liable for any monetary value over and above the quoted price of the service.
- Certain aspects of design dossier reviews are outside BSI's control and BSI is obligated to utilize clinician guidance to satisfy the Directive(s). Use of external non-BSI clinicians or external agency reviewers may impact timeliness for such products as those containing medicinal substances, animal tissue, or blood products.
- Following Conformity Assessment, BSI as the Notified Body may be required to review specific Post Market Clinical Follow-up (PMCF) data. The timing and need to review PMCF will vary by device and may require clinical expert review. Manufacturers who obtain certification and affix a CE Mark to a device will be fully responsible for the fees associated with PMCF review whenever this occurs (post-certification), BSI will endeavour to keep the fees for PMCF review reasonable.
- The official language of BSI and BSI's Competent Authority is English and all submissions, audit reports and test results should be in the English language. Submissions in other languages will result in additional review time and costs for translation which will be passed on to the applicant, and subject to BSI terms covering costs.
- Certificates for CE Marking are issued for 5 years and require a renewal process to be completed prior to the expiration date of the certificate. Certificates for ISO 13485 are issued for 3 years and require a renewal process to be completed prior to the expiration date of the certificate. Manufacturers are responsible for requesting renewal and will be required to provide supporting documentation.
- Additional assessment time may be required in order to address any major non-conformities raised during the audits. Assessment time is chargeable.
- The fees quoted are for illustration purposes only at current rates and are subject to annual review and adjustment.
- At its option, BSI may use the services of any of its international group companies to invoice fees on its behalf in order for the most efficient and convenient method to be used.
- Payment terms are 30 days from date of invoice.
- If the review takes less than 30 working days invoices will, where possible, be issued when the work is completed.
- If the review takes longer than 30 days, invoices will be issued on a monthly basis. Any remaining balance will be due at completion.
- All fees quoted in this proposal are exclusive of VAT which will be charged at the prevailing rate.
- BSI's audit and technical documentation review services are subject to availability.

Please complete the following items:

Client details

Company name:	Viamed Ltd
Address:	15 Station Road, Cross Hills, Keighley, West Yorkshire, BD207DT
Contact name:	Derek Lamb
Phone number:	01535634542
Email address:	Derek.lamb@viamed.co.uk

Invoice details

Company details (if different from above):	
Purchase Order number*:	

BSI shall address its invoices to the Invoice Address supplied by you as above. Any changes to the Invoice Address notified in writing to BSI will not affect invoices issued prior to such notification.

*A Purchase Order number is not a requirement for an invoice to be issued. Invoices will not be held if Purchase Order numbers are missing.

Declaration

We hereby authorise BSI to conduct the work pursuant to the terms of this document.

Signature: D Lamb

Full name: Derek Lamb

Date: 08 / 11 / 2018

Site Certificate issue notification should be addressed to:

Name: Derek Lamb

Email address: derek.lamb@viamed.co.uk

Estimated Date Documentation will be received by BSI: 8/11/2018 (DD-MM-YY)