

CLIENT DETAILS / QUOTE APPLICATION



To enable an accurate quotation to be prepared, the following information is necessary. All information received is treated in strict confidence.

Part A – Please complete for all management system certification (include reference to any attached supporting documentation).

COMPANY NAME:	CONTACT :
Address :	Position :
	Telephone No :
	Fax No :
Web address	E Mail:
Name and address of parent company (if applicable)	
DETAILS OF OTHER LOCATION(S) TO BE CERTIFIED include address, activity and numbers of staff	
If more than one location, do you want an individual assessment and certificate for each site? YES / NO / Not Applicable	

EMPLOYEES: Total in Administration: Total in Management positions: Total in Design: Total in Production/Operation: Others, please specify (e.g. off-site work / part-time personnel):	REQUIRED SCOPE OF CERTIFICATION
	Permitted exclusion(s) (ISO 9001 & ISO 13485 & GDPMD applicants only):

TO WHICH STANDARD IS CERTIFICATION BEING SOUGHT? (please check <input checked="" type="checkbox"/> the relevant standard(s))		
ISO 9001 <input type="checkbox"/> ISO 14001 <input type="checkbox"/> ISO 45001 <input type="checkbox"/>	FSMS/ ISO 22000 <input type="checkbox"/> HACCP/ MS 1480 <input type="checkbox"/> GMP/ MS 1514 <input type="checkbox"/>	ISO 13485 <input type="checkbox"/> GDPMD <input type="checkbox"/> IATF 16949 <input type="checkbox"/> AS 9100 <input type="checkbox"/>
If Others (please specify):		

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CERTIFICATIONS ALREADY HELD (please attach copies of certificates)			
Standard	Certification Body	Date awarded	Current, lapsed or suspended

OTHER INFORMATION	
Do you require a quotation for a Pre-assessment Audit?	YES / NO
Is this a transfer from another certification body?	YES / NO
Does your Company work shifts?	YES / NO
	How Many? (if YES):
How long have you been operating your management system?	
Do you operate an integrated management system (IMS)?	YES / NO
If yes, please give details (e.g. IMS for quality, environment and health & safety & HACCP)	
Date Pre-assessment required (<i>if applicable</i>)	
Target Assessment date	
How did you hear of KGS?	
The name of any consultancy service used in developing/maintaining the management system	

PRODUCTS / SERVICES AND PROCESSES
Please give details of products and / or services provided
LEGAL & REGULATORY REQUIREMENTS: Please state any applicable to the product or service
Please describe the main processes used in manufacturing your products or supplying your services. Please also give details of outsourced technical processes:

If possible, please supply a copy of your company brochure/profile and organisation chart.

Applicants for ISO 14001 certification must also complete Part B

Applicants for ISO 45001 certification must also complete Part C

Applicants for HACCP certification must also complete Part D

Applicants for ISO 13485 certification must also complete Part E

Applicants for GDPMD certification must also complete Part-F

All applicants must sign on Page 7 of form and return completed form to KGS.

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Part B – Please complete only for ISO 14001 EMS certification

CONTACT (If different to Part A - include name, position, telephone number and email address)

For each location to be certified please enclose a site plan, if available, which shows the following details

- Size of site:
- Location of site including neighbours: .
- Site services including drainage :
- Emission and discharge points:
- Any part of the site subject to separate control :

ENVIRONMENTAL ASPECTS AND IMPACTS

Outline environmental aspects and impacts that you have identified as significant
(*e.g. transport exhaust emissions – air pollution and climate change*)

LEGAL/REGULATORY DOCUMENTATION

Please list any consents, licences, permits, authorisations etc held

SUB-CONTRACTED ACTIVITIES

Please list

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Part C – Please complete only for OHSAS 18001 & ISO 45001 certification

CONTACT (If different to Part A - include name, position, telephone number and email address)

For each location to be certified please enclose a site plan, if available, which shows the following details

- Size of site
- Location of site including boundary, neighbours and general public
- Any part of the site subject to separate control

HEALTH AND SAFETY HAZARDS

Outline occupational health and safety hazards and risks that you have identified as significant arising from operations

(e.g. working at height – risk of falls from height)

HAZARDOUS MATERIAL USED

Outline the list of hazardous material used in the processes/operations of your organization

Hazardous Material includes Hazardous Gases, Flammable liquids, Flammable solids, Oxidizers/organic peroxides, Toxic and infectious substances, Radioactive material, Corrosives, Miscellaneous hazardous materials etc.

(eg. Asbestos, lead paint etc.)

LEGISLATIVE AND REGULATORY REQUIREMENTS

Please list the key legislative and regulatory requirements

SUB-CONTRACTED ACTIVITIES

Please list

NUMBER OF EMPLOYEES

Working at organization premise:

Working away from organization premise (eg. construction project site, maintenance project site):

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Part D – Please complete only for HACCP certification

CONTACT (If different to Part A - include name, position, telephone number and email address)

For each location to be certified please enclose a site plan, if available, which shows the following details

- Size of site:
- Location of site including neighbours: .
- Pre-requisite Programme (PRP) practices in place? (Yes / No)
- Describe your product & intended use(or attach company profile)

Process flow

Outline the process flow.

(e.g. flow shall cover incoming to outgoing or enclose separately)

HACCP plan details: (ie.How many process involved & plan reference)

Please state total number of CCP's established?

LEGAL/REGULATORY DOCUMENTATION

Please list any consents, licences, permits, authorisations etc held

SUB-CONTRACTED ACTIVITIES

Please list

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Part E – Please complete only for ISO 13485 certification

CONTACT (If different to Part A - include name, position, telephone number and email address)

For each location to be certified please enclose a site plan, if available, which shows the following details

- Size of site:
- Location of site including neighbours: .
- Any part of the site subject to separate control :

Type & Classification of Medical Device:

Rule of Medical Device:

Please tick the following in which category suitably to your product

- | | |
|---|---|
| <input type="checkbox"/> Non Active non implantable device | <input type="checkbox"/> Non Active Implantable device |
| <input type="checkbox"/> Devices for wound care | <input type="checkbox"/> Non Active Dental Device and accessories |
| <input type="checkbox"/> Non Active device other than the above | |

- | | |
|---|---|
| <input type="checkbox"/> Active Non implantable device | <input type="checkbox"/> Devices for Imaging |
| <input type="checkbox"/> Devices for Monitoring | <input type="checkbox"/> Devices for radiation/thermo therapy |
| <input type="checkbox"/> Active device other than the above | |

- Active implantable medical device
- Implantable device other than the above

In vitro Diagnostic Device (underline the exact category specified)
(Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Haematology/Haemostasis or Immuno hematology) Microbiology, Infectious Immunology, Histology/Cytology, Genetic Testing

In Vitro Diagnostic Device other than the above.

Sterilization applicable (or) Sterilization not applicable
(if Sterilization is applicable state the type of sterilization used).....

Devices incorporating/utilizing specific substances/technologies

Outline Product intended use:

LEGAL/REGULATORY DOCUMENTATION

Please list any consents, licences, permits, authorisations etc held.

SUB-CONTRACTED ACTIVITIES

Please list

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Part F – Please complete only for GDPMD certification

CONTACT (If different to Part A - include name, position, telephone number and email address)

For each location to be certified please enclose a site plan, if available, which shows the following details

- Size of site
- Location of site including boundary, neighbours and general public
- Any part of the site subject to separate control

Name of the product	Manufacturer	Class	Rule	Origin	CE No/MoH Regn. No.	Distribution Area

LEGISLATIVE AND REGULATORY REQUIREMENTS

Please list the key legislative and regulatory requirements

(Enclose the list of product profile for which you are performing distribution activity)

SUB-CONTRACTED ACTIVITIES

Please list

Declaration - Please complete for all management system certification

KGS personnel might contact you for further information necessary for providing a proposal for services. This form must be signed by an authorised representative of the applicant to confirm the accuracy of the details provided, that the applicant will supply any information needed for the evaluation, and that upon certification, the applicant will comply with the KGS Regulations for Certificate Holders.

Signed: _____ Name (Please Print): _____ Date: _____

Office Use Only: EA Code(s): _____ NACE Code(s) : _____

HACCP Category: _____

Only for Medical device: Class: _____ Scope Code: _____ MDB Code: _____ CE if any NB number : _____

PLEASE RETURN TO: KGS Certification Sdn. Bhd., No.15 BLM 5/4, Bandar Laguna Merbok, Sungai Petani, Kedah Darul Aman, Malaysia.

Tel: +60 (04)- 4411524 Fax: +60 (04) 4410610

E-mail: admin@kgscert.com