**IVDD REQUEST FOR SERVICES FORM**

**IN-VITRO DIAGNOSTIC MEDICAL DEVICES (98/79/EC) & QUALITY MANAGEMENT SYSTEM CERTIFICATION SERVICES**

|  |  |
| --- | --- |
| Lloyd’s Register (LR) is a UK based Notified Body for medical devices and in vitro diagnostics and offers product and systems certifications with a high level of technical expertise and competence. Our team of medical device experts has experience in providing certification services to large multi-national organisations and small start-ups in a variety of areas including orthopaedics, cardiovascular, wound care, ophthalmic devices, active devices, devices with ancillary medicinal products, devices utilising animal tissue, software and in vitro diagnostics.  To allow us provide you with an accurate quotation for the services that you require, please complete the form in full and return it to [enquiries-uk@lrqa.co.uk](mailto:enquiries-uk@lrqa.co.uk). If based in the USA please return the completed form to [sales-usa@lrqa.com](mailto:sales-usa@lrqa.com) | |
|  | |
| The **Guidance Notes** below clarify what information we require in the various sections of the form. | |
|  | |
| Please note certification to the IVDD Directive can only be provided to ‘manufacturers’ defined as organisations placing products on the market under their own name and entity, whether or not they are responsible for the manufacturing activities.  **Thank you for your interest in LR. Please return this form to LR, with full device details and any other relevant information, such as IFUs, intended use statements, marketing literature or links to your website that would assist us in processing this application.** | |
|  | |
| **Enquiry ID reference number** | (for office use only)  (Format IVDD/Manufacturer/date form completed (e.g. IVDD/Prod ltd/020816) |

|  |
| --- |
| **GUIDANCE NOTES**  **SECTION A** |
| We require full details of the company, sites, activities, employee numbers, contact details, and the date of form completion.  If based outside the EU, please provide details of your authorised representative. |
|  |
| **SECTION B** |
| We need you to tell us what services you require and check the option you require. |
|  |
| Our **Gap Analysis assessment** is an optional pre-approval service that we offer to assist you in gauging your readiness for assessment and to give you an early indication of any issues. |
| **Quality system certification** is the formal two-stage certification process against the assessment standard indicated and you can choose either or both, to suit your requirements. |
|  |
| You must define the scope of approval that applies to the specific activities controlled by your quality management system. The layout below may be used as a guide to write your approval scope: |
|  |
| MAIN ACTIVITY / SERVICE ASSOCIATED PRODUCTS ANY ADDITIONAL ACTIVITIES |
| *e.g., Design, manufacture. e.g., HIV assays etc. e.g., Installation, service, repair, etc.* |
|  |
| You must identify the conformity assessment route you require for the **In-Vitro** **Medical Devices Directive - 98/79/EC** and indicate this on the form. |
|  |
| **SECTION C** |
| We require details of any current management system or regulatory approvals held and also copies of all certificates. Certificates can be e-mailed with the form, attached as PDFs. |
|  |
| **SECTION D** |
| We need you to provide details of all the device types that you wish to be included in the scope of the approval. We require specific information about your products and the description **is the intended use** of the IVD device including the **condition analyte or disease marker** that is being assessed and the type of **technology** used *(for example, immunoassay or PCR)*. Brand names / trade names are not required, but can be added if known. We also need to know the classification and under which classification rule they fall, the intended purpose of the device (indications for use), product brochures / literature or a web link where we can find the information. |
|  |
| For Sterile devices, please specify the method used and indicate if sterilisation is performed in-house. |
| **SECTION E** |
| If you have any sub-contractors who perform critical activities for you, you need to provide us with the details, *for example, they manufacture critical components on your behalf, sterilise products, etc.* |
|  |
| **SECTION F** |
| Please provide details of the language of your management system, so that we can define any need for specialist resource. |
| The more details we have, the more accurately we can assess your needs and meet your requirements.  **SECTION G**  Please provide details for each Annex II List A device to be included in the scope of this application. |

## SECTION A - Information about your company

|  |  |  |  |
| --- | --- | --- | --- |
| Legal Company name: |  | | |
| Main contact name: |  | | |
| Position in company: |  | | |
| Phone number: |  | Mobile number: |  |
| E-mail: |  | | |
| Company Reg No: |  | Date Form Completed: |  |

# Main site

|  |  |  |  |
| --- | --- | --- | --- |
| Company address: |  | | |
| City / country: |  | | |
| Post / ZIP Code: |  | Number of employees and Shift system: |  |
| Activities on site: |  | | |

# Other sites (if your quality management system includes more sites, please list them here)

|  |  |  |
| --- | --- | --- |
| Site location: | Activities on site: | Number of employees and shift system: |
|  |  |  |
|  |  |  |
|  |  |  |

*If there are further sites, please provide the same information as above on an additional sheet.*

# Authorised European Representative (if company is not resident in EU)

|  |  |
| --- | --- |
| Legal Company Name |  |
| Company Address |  |
| Representative Title / Name / Position |  |

**SECTION B - Services You Require from LR**

**Gap Analysis (Optional)**

Please tick if you require a pre-assessment service to review your readiness for compliance

**Quality System Certification**

ISO 9001:2015

EN ISO 13485:2016

MDSAP ISO 13485 Certification (Request for Services Form – Medical Device Single Audit

Program MDSAP to be also completed)

*(Please check boxes as required, multiple options possible)*

# Scope of Approval

|  |  |
| --- | --- |
| Suggested Scope of your quality system: |  |

**Medical Devices Directive (98/79/EC) - CE Marking Services**

CE Certification to IVDD 98/79/EC  Transfer from another Notified Body

**For Transfers, please state reason below;**

|  |
| --- |
|  |

Please indicate which conformity assessment route you require:

**ANNEX IV** (Full Quality Assurance)

**ANNEX VII** (Production Quality Assurance)

**ANNEX III.6**(for Non-Annex II Self-test devices only)

For a description of all the above services, please refer to the Appendix at the back of this document or discuss with a Business Development / Account Manager.

**Special requirements for LR Auditors:**

Please provide details of any personal protective equipment and any specialised training or any special security required by your Company.

|  |
| --- |
|  |

**SECTION C - Existing Approvals held by your company**

Do you have a current certificate for any of the following:

ISO 9001:2015

ISO 13485:2016

In-Vitro Diagnostics Medical Devices Directive (98/79/EC)

*Please check the boxes that apply*

Please provide details for all existing approvals:

|  |  |
| --- | --- |
| Who issued the Certificate? |  |
| What is the Scope of Approval? |  |
| Date of last audit? |  |
| Expiry date of approval? |  |

Do you wish LR to take over these approvals?  YES  NO

Certificates attached  YES

**SECTION D - Information about your products**

Please complete the following table with the specific information about your devices to be included in the scope of this application. Copies of any product literature or website addresses should be included

# Products applicable to the application (Please add extra rows if required)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Device Name | Device description and Intended use | Classification  ***Annex II List A, Annex II List B, self-test devices*** | Justification for Classification | Sterilisation Method  *(if applicable)* | Sterilisation Location  (if applicable) |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

For Annex II List A devices, please complete Section G of this form.

**Accessories**

If any accessories are included in any of the above devices, please provide details

|  |
| --- |
|  |

**Novelty**

Is the device a new development?

YES  NO

Does the device feature any novel features such as intended use, technology or material? If so please provide details below

|  |
| --- |
|  |

**SECTION E - Sub-contractor information**

Do any sub-contractors who perform critical activities for you?  YES  NO

If ‘Yes’, then please provide details:

|  |  |
| --- | --- |
| Name and address: |  |
| Activity performed: |  |
| Details of any approvals: |  |

Please continue on a separate sheet as necessary and attach copies of any relevant certificates

**SECTION F - Additional information**

What language is your quality system written in?

|  |
| --- |
|  |

***Note: LR requires product technical files or design dossiers to be submitted in English***

Please use the area below to provide any additional information that will assist in processing your application?

|  |
| --- |
|  |

When do you anticipate that your company will be ready for assessment?

|  |
| --- |
|  |

***If you manufacture Annex II List A devices - You MUST fully complete the section on the next page***

**SECTION G - Design Examination (Design Dossier review) – Annex II List Adevices only. Please note batch verification will also be required for Annex II List A devices.**

Please provide as much detail as possible for the following. Use attachments if this is easier for you.

*Note:* ***LR requires product Design Dossiers to be submitted in English***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **Name or Type of device:** Please include a description of the range of products or variants that are included in the Design Dossier.  |  | | --- | |  |  1. **Intended Purpose of device:** Please include any particular claims or indications to be made.  |  | | --- | |  |   *If ‘YES’, please specify the material and animal origin, including any EDQM certificate information:*   1. **Can you provide three lots of each product for the establishment of batch verification criteria**  YES  NO   *If ‘YES’, please indicate when the lots would be available for*   1. **Is the device sterile?**  YES  NO   *If ‘YES’, please specify the method and details of any subcontractors used:*   |  | | --- | |  |  1. **Are any other aspects of the device manufacture performed by sub-contractors?**   YES  NO  *If ‘YES’, give details of sub-contractors, including any approvals held:*   |  | | --- | |  |  1. **Does the Design Dossier contain all information and data required to assess the design?**   YES  NO   1. **Can all necessary information (Design Dossier & supporting data) be submitted for remote assessment?**   YES  NO   1. **What is your target date for the assessment?**  |  | | --- | |  |   **Appendix 1: Description of LR Product Certification and Quality Management Services**  **ISO 9001:2015:** ISO 9001:2015 (UKAS) is an international standard that specifies requirements for a quality management system and is applicable to all industries and businesses. The 2015 standard replaces the 2008 version and there is a three-year transition period in place from publication in September 2015.  **ISO 13485:2016 (UKAS):** ISO 13485 is an international standard recognized for medical device QMS registration. It helps manufacturers consistently manufacture devices that are safe and fit for their intended purpose and meet regulatory requirements for manufacturing control. LR is an accredited third party (UKAS, SCC) that conducts on-site assessments and makes recommendations.  **ISO 13485:2016 plus Medical Device Single Audit Program (MDSAP):** LR is an accredited Registrar by the Standards Council of Canada(SCC) to conduct ISO 13485 registration and is also authorised to conduct MDSAP Audits. MDSAP allows medical device manufacturers to have a single audit of their Quality Management System (QMS) which satisfies the requirements of multiple regulatory jurisdictions: **Australia -** The Therapeutics Goods Administration, **Brazil -** The Brazilian National Health Surveillance Agency, **Canada -** Health Canada, **Japan -** The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency, **United States -** U.S. Food and Drug Administration’s Center for Devices and Radiological Health).  **CE Marking Service:** All LR technical and design dossier reviews are conducted as a dedicated service with time booked in the product assessor/product specialists’ diary for the assessment. This provides you with you with a clear timeline for assessment and visibility on the process. |
|  |