DEKRA Certification UK Ltd
Customer Information Form

Thank you for considering DEKRA Certification UK Ltd assessment services

To best serve you and provide you with the most accurate quotation for certification services, please complete this questionnaire. An offer will be prepared using this information.

Any information provided will remain strictly confidential.

DEKRA Certification UK Ltd reserves the right to share information with DEKRA Certification Medical Business Lines

DEKRA Certification UK Ltd
Stokenchurch House
Oxford Road
Stokenchurch
Bucks
HP14 3SX
+44 330 9120 368
certification.uk@dekra.com
Company Registration Number 13129030

Section 1: Company Information

1.1: Address

Legal Company Name	
Trading as (if applicable)	
1st Line Address	
2nd Line Address	
City	
County/State	
Postal/Zip Code	
Company Registration Number	
VAT Number	
Website	
Are you an existing DEKRA notified body Client?	If yes, please state the Notified Body (either DEKRA BV or DEKRA GmbH)

1.2: Contact Details

Primary Contact	
Title	

Contact Name	
Position	
Email address	
Telephone Number	

Secondary Contact	
Title	
Contact Name	
Position	
Email address	
Telephone Number	

1.3: UKRP

UK Responsible Person (For UKCA applications only)	
Company	
Title	
Contact Name	
Position	
Email address	
Telephone Number	

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1st Line Address	
2nd Line Address	
City	
County	
Post Code	

1.4: Other Information

Please describe the core business of your company	
Is your company part of a larger organization. If yes please give the name of the parent company	
How many employees work at your company? Please state in full time equivalents (FTE)	
How many employees are working under the scope of a quality system related to medical devices or IVD devices? (this includes those involved in the design and manufacture of medical devices/IVDs)	
Number of FTE above is based on the number of employees corrected for personnel working part-time:	
Number of FTE above includes an estimate of the average number of temporary personnel employed by the organisation:	
Number of FTE above is corrected for employees performing activities partially in scope or not in scope of the inquiry:	
Number of FTE above is corrected for personnel who perform activities that are considered repetitive (cleaners, security, transport, sales, call center etc.):	
Number of FTE is corrected for temporary unskilled personnel employed in considerable numbers:	

Please state number of shifts, employees per shift and working hours	
Does your business work over multiple sites? If so please state how many	
Have you worked with a quality management system consultant in the past 3 years? If yes please give the name of the consultant	
Please indicate whether consultancy relating to UKCA certification is being or has been provided. If yes please give the name of the consultant or consultancy if different from above:	
How did you first learn of DEKRA ?	
Please list additional attachments to this document: e.g. brochures, existing certificates etc	

Section 2: Schemes and Markets

Are your products: (Select all that apply)

Medical Devices (Active)	Medical Devices (Non-Active)	Implantable Medical Devices	Ingestible Medical Devices	Active Implantable Medical Devices	In-Vitro Diagnostic Medical Devices	Other (Please Specify)
☐	☐	☐	☐	☐	☐	☐

Other:

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For which markets do you have commercial sales or intend to obtain approval for your medical devices?

Great Britain	Northern Ireland	European Economic Area (Including Republic of Ireland)	MDSAP Jurisdictions (Australia, Brazil, Canada, Japan, US)	Other (Please Specify)
☐	☐	☐	☐	☐

Other:

For which DEKRA Certification services would you like to receive a quotation?

QMS			
ISO 13485:2016	☐		
ISO 9001:2015	☐		
MDSAP	☐		
UK MDR 2002			
Part II (Medical Devices)	New Application ☐	Abridged* ☐	UKCA+** ☐
Part III (Active Implantable Medical Devices)	New Application ☐	Abridged* ☐	UKCA+** ☐
Part IV (In Vitro Diagnostic Devices)	New Application ☐	Abridged* ☐	UKCA+** ☐
European Economic Area			
MDR 2017/745	☐		
IVDR 2017/746	☐		
CE EU Legacy – MDD	☐		
CE EU Legacy - IVDD	☐		

*DEKRA's abridged process allows manufacturers to leverage existing CE Certification to evidence conformity to some of the requirements of UKCA certification. This has the potential to reduce both time and cost incurred. The abridged process is not available to class III devices unless an existing DEKRA client.
**A DEKRA EU Notified Body must be the third-party conformity assessment that was involved with CE Certification to allow combined sampling plans and dual assessments.

Is this a voluntary transfer of certification/UK Approved body?	
Please indicate the reason for requesting the voluntary change:	
Please indicate the expiry date of certification	

Section 3: Product Related Questions

For UKCA and CE applications only

Please complete the product overview sheet embedded below. List all devices which you are seeking certification for. Please ensure details are up to date and correct as this will form the basis of your quotation and schedule of work.

Worksheet in https dekracloud-my.sharep

Are any of your medical device products currently CE marked with another notified body or UK Approved body besides DEKRA. If so pelase identify this organisation.	If yes please state which Notified/Approved body with NB/AB number.
Has an application with another Notified Body / UK Approved Body with regard to the same device(s) been withdrawn prior to the certification decision of that Notified Body / UK Approved Body?	If yes please state which Notified/Approved body
Has any previous application with another Notified Body / UK Approved Body for the same device and conformity assessment been refused by another Notified Body / UK Approved Body?	If yes please state which Notified/Approved body
When will the technical documentation be ready for review?	

Deliverables

In this section we ask you to complete the second column and submit the documents as attachments to the application form.

Application Requirement	**Document Reference** Please include document references in this column and submit the documents as attachments or indicate not applicable
Contract/Agreement for appointed UK Responsible Person	
Device Classification.	
NBOG Expression codes. (NBOG 2009-3)	
Conformity assessment routes for UK MDR 2002	
Draft UKCA Declaration of conformity and Confirming DEKRA Certification UK Ltd is identified as UK Approved Body.	
Draft UKCA Labels, IFU. Promotional Material	
General Safety and Performance Requirements versus Essential Requirements, where CE-certification is under the EU Regulations	
Designated Standards.	
Up to date CER/CEP [Including non-EU safety and performance data].	
Up to date PMS data, PMCF	
Vigilance data [Including non-EU safety data].	
Formal statements related to the use of: 1. derivatives of tissues or cells of human origin 2. derivatives of tissues of cells of animal origin 3. medicinal substances 4. substances or combination of substances that are absorbed or locally dispersed into the human body 5. presence of CMR and/or endocrine-disrupting substances, including phthalates	

6. Nanomaterials	
Information for class III devices or for class IIb devices intended to administer and/or remove a medicinal product the manufacturer has, prior to its clinical evaluation and/or investigation, consulted the expert panel, with the aim of reviewing the manufacturer's intended clinical development strategy and proposals for clinical investigation.	
In case the device was certified under **UKCA/ CE MDR /CE MDD Legacy** 1. Copy of the last issued certificate(s) together with certificate history 2. A description of any design intended use modifications introduced to comply with the UKCA MDR 2002 3. Outputs from Third Party Audits and Technical Assessments/Sampling Plans 4. Copy of the Original Animal Tissue SER 5. EU NB/UKAB reports associated with the Animal Tissue SER 6. Competent Authority or MHRA comments on the Animal Tissue SER	

Requirements for IVD devices	
If applicable, formal statements related to the intended use (near patient testing, companion diagnostics or self-testing) and the conformity assessment route.	
Procedures and documentation on manufacturer's batch release for-Annex II-List A products.	
For self-testing: - Test reports, including results for test performed at the intended users. Data showing the suitability of the device in relation to its intended purpose	

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Section 4: QMS Related Questions

All Applications

Has your quality system been previously certified to other standard(s)?	If yes please state the standards and the certificate issuer (CAB/Notified body/UK Approved Body)
Do you have a fully documented Quality System?	
Has a full cycle of internal audits been conducted?	
Has a Management Review been conducted?	
When will your Quality Management System be ready for review by DEKRA?	
What language is the management system written in?	
Have Any external audits been performed?	If yes please state the standards and by whom (CAB/Notified body/UK Approved Body)
What is the scope or proposed scope of the Quality Management System?	

Which activities are covered by your Quality System? (check all that apply)

☐ Design and development ☐ Service ☐ Production

☐ Sales ☐ Outsourced production ☐ Marketing

☐ Purchasing ☐ Controlled environment

☐ Staff / Management Responsibilities (incl. QA/RA)

☐ Sterilization (in House) Type: _____

☐ Sterilization (outsourced) Type: _____

☐ Storage ☐ Distribution ☐ Installation

☐ Other Type: _____

1 QMS DELIVERABLES - FOR UKCA ONLY applications

In this section we ask you to complete the second column and submit the documents as attachments to the application form.

Application Requirement	**Document Reference** Please include document references in this column and submit the documents as attachments or indicate not applicable
QMS activities covered in this application, procedures in place to ensure the QMS remains adequate and effective the QM must include UKCA particulars.	
Top level strategy for UKCA implementation	
PMS process, and PMCF/PMPF plan	
Vigilance process and reporting to MHRA.	
The processes used to communicate with authorities.	
Virtual manufacturing- manufacturers agreement with OEM and VM and associated procedures.	
The procedures in place to keep up to date the clinical or performance evaluation evidence.	
The labelling process.	
Third Party Audit Outcomes, copies of all applicable audit reports, where applicable.	

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Section 5: Critical Subcontractors and Suppliers

Company name / address*	Type of service to Applicant	QMS standard	Name Certifier	Certificate number	Expiry date

***Full address preferred, the minimum is city, state and country. Please attach a copy of registration certificates available for the subcontractor and supplier.**

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Section 5: Validity and Signatures

1. I declare that the information provided in this form is accurate and correct, representing the correct information at the date of signing this document.
2. That the approved body/ notified body will be granted access to the technical documentation according to UK MDR 2002 / Annex II and III of the MDR 2017/745, EU MDD Legacy Device 93/42/EC as amended. Annex II and III of the IVDR 2017/746 or IVDD 98/79/EC
3. That the UK Approved Body will be granted access to the technical documentation according to the requirements of the Great Britain (SI 2002 NO 618, as amended) (UK MDR 2002) as amended.
4. For UKCA-certification of a product with valid CE-certification delivered by a DEKRA Notified Body, where the applicant requests the CE-certification evidence is used as part of the UKCA-certification conformity assessment, DEKRA Certification UK Ltd shall have full access to the documents lodged with the DEKRA Notified Body via internal transfer.
5. Where applicable for abridged conformity assessments, the manufacturer declares the product under UKCA is the same as certified under CE certification.
6. If the device was certified under CE MDR /CE MDD Legacy, it is confirmed that the device was marketed for the same intended purpose and indication of use.
7. The product information supplied in Client Information Form is correct and/ or a new version is supplied with this application with clearly identified changes.
8. All required documents for this application and any further requests to support conformity to Great Britain (SI 2002 NO 618, as amended) (UK MDR 2002), shall be provided in English.

Name	Date
Company & Function	Signature

Please return this Company Information Form to the appropriate DEKRA Certification Office listed below.

Please attach the following where applicable and available:

- Brochures describing your company and products.
- Relevant existing quality system certificates of your manufacturing sites or subcontractors relating to the products to be certified or UKCA marked.
- Existing CE / UKCA certificates that may be relevant to the product range for which UKCA certification is required.
- Any information about previous (refused) CE Notified Body application(s) or UKCA UK Approved Body application(s), related to the product for which certification is sought.
- Other relevant information that could be considered helpful in processing a quotation.

Please don't hesitate to contact us if you have any questions.