JS GROUP

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UK Medical Device Registration Services
United Kingdom Responsible Person (UKRP)

Since 1st January 2021, it is a legal requirement for all foreign medical device manufacturers to register their products with the Medicines and Healthcare Products Regulatory Agency (MHRA) using a UKRP before placing their products for sale on the United Kingdom market, even if they are originally CE-marked and currently on-sale.

JS Group provide a full range of professional regulatory services to medical device manufacturers and importers at very realistic costs.

- The regulations for marketing authorisation of medical devices in the UK changed in January 2021 after the UK left the European Union. The original CE mark you obtained in one of the EU member states will be replaced by the **United Kingdom Conformity Assessment** mark (UKCA) on 1st July 2023
- Your current Authorized EC Representative is no longer legally valid to authorize you to place your products on the UK market and you must, by law, now appoint a UKRP to do this for you, even with the current CE mark on your product.
- A UKRP will be your legally appointed representative to represent and advocate for you with the MHRA. Your registration with MHRA will need to be renewed on an annual basis to remain valid in order to continue selling your products in the UK.

- Fast, reliable and professional regulatory services
- Experienced medical device specialists with global expertise
- Cost effective solutions with a range of flexible service options
- Guidance, advice and support included as part of our service
- Regular communication and client reporting
- Fully managed process from initial registration to CAPA management
- Thorough document examination and advice on compliance and conformity
- Free advice on all regulatory procedures including UKCA submissions
- Regular updates from MHRA as changes are promulgated
- Guidance on labeling and packaging to meet regulations

Based at the Innovation Hub at Cranfield University Technology Park, JS Medical is the medical device business within the JS Group with over 75 years in the global medical device industry. We have helped numerous internationally expanding companies from from the USA, Japan, China, Europe, Israel and Turkey with their international business development and regulatory strategies.

Please contact us for further technical and price information on +44 (0)1234 888955 or +44 (0)7774 930316 or at info@js-group.global

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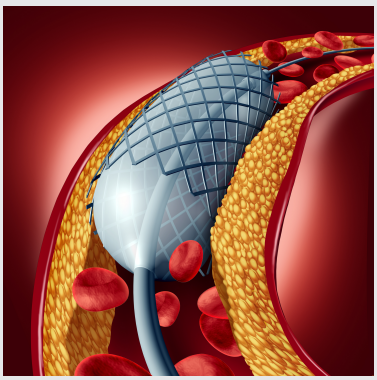
Our UKRP services cover the following class of medical devices:

- Class I
- Class II(a) and Class II(b)
- Class III
- IVDD
- Active Implantable Devices
- Devices under clinical trial

What's included in your UKRP service package?

- Annual registration/subscription fee, covers all of the legally required obligations and services required by the UK Competent Authority (MHRA) for one year.
- Initial JS Medical registration fee. Covers all administration costs and professional services to ensure successful registration of both the manufacture and up to 1,000 devices on the MHRA database.
- Initial technical file review and examination of all mandatory documents.
- MHRA registration and submission fees.
- Notification support in the event of a product recall or other advisory notices from MHRA.
- Follow-up actions with MHRA and the manufacturer with notices from MHRA and requests for product information.
- Advice on Corrective and Preventative Actions (CAPA), and recalls.



Documents Required for MHRA Product Registration

- Letter of Designation (authority to act as UKRP)
- Letter of Engagement for UKRP Services
- Completed Application Form
- Mutual NDA
- CE or UKCA Certificates
- ISO and/or Quality Management Certificates
- Design Examination Certificates
- Declaration of Conformity (DOC)
- Product Technical Files
- Certificate of Product Liability Insurance
- Instructions for Use (IFU)
- Clinical Study Abstracts
- Performance Studies
- Risk Analysis and Safety Data
- Images of Labels
- Company Profile

Full regulatory details concerning medical device in the UK can be found on UK.Gov/MHRA

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