



Rocketmedical

Customer Information Bulletin: Third Party Supplier Agreements

Dear Customer,

Following the introduction of the EU Tissues and Cells Directive, we have had multiple enquiries to approve or provide 'Third Party Supplier Agreements'.

Background:

It has been a regulatory requirement since Jan 1st 2000 that any EU supplier of sterile medical devices is registered with an approved body and must provide evidence that they have been assessed and certified as meeting the requirements of Directive 93/42EEC for the manufacture of medical devices. Fulfilling the requirements of the above Directive entitles a manufacturer to mark its products with an appropriate CE mark.



However, the stringent requirements of the Directive have not included some laboratory equipment such as plastic ware and as a result, some confusion has arisen concerning the supply/quality of a wide range of devices in regular use in IVF Units and laboratories.

Rocket Medical plc has been assessed and approved as meeting the requirements of Directive 93/42EEC since 1993 and prior to this, the company had in place the UK's GMP Registration. As a result, all of our devices for IVF and other applications are CE Marked.

Furthermore, the company's Design Management and Quality Systems have been assessed and certified as meeting the requirements of both ISO13485 and ISO9001

Copies of these certificates may be downloaded from the company's web site.



You can be reassured that the majority of the needs of your 'Third Party Supplier Agreements' are already enshrined as primary requirements of meeting the Directive 93/42EEC and ISO Systems. A copy of the company's own Supplier Agreement can be obtained by calling our Customer Services Team or may be downloaded directly from our web site: www.rocketmedical.com.

Frequently Asked Questions:

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| Do you have regular audits? | YES, we have 6 monthly audits, performed by an independent body as part of our CE/ISO registrations. |
| Do you have a Quality System? | YES, this is a key requirement of CE/ISO registration. |
| Will goods supplied be fit for purpose? | YES, this is a key requirement of CE/ISO registration. |
| Do you have an Agreement document available? | YES – Although many of these requirements are already covered by CE registration, Rocket Medical have assembled a formal Third Party Supplier Agreement to help our customers to comply with the new Directive.
<i>A copy can be downloaded from our web site or can be obtained by contacting our Customer Services Team.</i> |

**If you have any further questions, please contact our
Customer Services Team for assistance: 0191 419 6988**