



European Union Authorised Representative Service Agreement

Agreement made between the Client			
Address			
Tel No		Fax No	
Contact		Email	

And The Provider: M. Devices Group (herein referred to as MDG)			
Marlborough, Riding Street, Southport, PR8 1EW, England.			
Phone: +44 1704 544 944 Fax: +44 1704 544 050 E-mail: ecrep@mdevices.net			

* Please select terms **MDD** for Medical Devices, **IVD** for Invitro Diagnostics, **PPE** Personal Protective Equipment

Services to be provided: MDG will act as the client's European Union Authorised Representative.

* MDD	Register your devices with the Competent Authority
* MDD	Under Article 14 of the Council Directive 93/42/EEC will report incidence, complaints and other notifications to the relevant Competent Authority for your organisation, with your agreement.
* IVD	Register your devices with the UK Lead Competent Authority & other CA's by agreement
* IVD	Under the Council Directive 98/79/EC will report incidence, complaints & other notifications to the relevant Competent Authority for your organisation, with your agreement
* PPE	Register your devices with the Competent Authority if necessary
* PPE	Under Article 8 of the Council Directive 89/686/EEC act as the Authorized Representative for the Manufacturer (Client) and where required report incidence, complaints and other notifications to the relevant Competent Authority

Help with Reporting:

- MDG will provide guidance to you our client where required, as to what events, incidence, complaints are reportable and a copy of Vigilance guidelines.

What do you need to do:

- If you are the manufacturer or distributor, first placing the devices in the market, you must ensure that your organisation, your distributors and their customers have procedures in place which will permit the reporting of all reportable events to MDG, your European Union Authorised Representative. You and they must be able to manage an effective and fast Product Recall.

How to report:

- We will provide you with copies of the Vigilance & Other appropriate guidelines, which provide templates for reporting all reportable events.

Special People make our Service Special
 Visit our Web site: www.mdevices.net *e mail* eurep@mdevices.net
 M Devices Ltd Reg:England 3693058 Reg Office: Marlborough House, Riding Street, Southport, PR8 1EW, UK.
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How to label your Packaging, “Instructions For Use” & Manuals of your Devices: You need to clearly state our full contact information:

Authorised Representative in the European Community
 M. Devices Group, Marlborough House, Riding Street, Southport, PR8 1EW, UK.
 Tel: +44 1704 544 944 Fax: +44 1704 544 050 Email: ecrep@mdevices.net

*** See Annex I for Recommended Symbols**

Your contact in MDG:

- Is Paul Shane Bennetts who will liaise between you and MDG’s technical client advisors. MDG may change your contact in MDG from time to time.

Our Promise:

- To provide you with a responsive, professional, helpful and friendly service.
- To help you find answers to questions you may have, either through ourselves or others.
- To acknowledge your faxes and emails speedily
- To listen carefully to any complaints you may have about our service and to respond to you within three days with corrective action and a genuine apology.

Periodic Reviews:

- We will undertake annual reviews of your products to check that your declaration remains current.

The Cost:

* MDD	Your annual fee is \$2250 Euros €2100.
* IVD	Your Annual fees are \$1500 Euros € 1400 for registering with the UK Lead CA, & \$750 Euros € 700 for the other EU member states CA (Competent Authorities).
* PPE	Your annual fee is \$2250 Euros €2100.

- There are no extras or hidden charges, you will not pay any other costs, other than any Competent Authority's Fees on Registration / Amendments (presently approx. US\$130 Euros €125), plus wire charges approx US\$35 Euros €33.
- In return we ask you to sign this 3 years agreement & the annual fee will remain fixed for 3 years.

When and How do you pay:

You pay your annual fee each year on the commencement date & anniversary of the payment date. Payment is by wire transfer from your bankers to MDG’s Bankers:

US\$ Dollar Payments	Lloyds Bank PLC, Details will be forwarded by Email for Security Reasons
Euros € Payments	Bank of Ireland Details will be forwarded by Email for Security Reasons

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Commencement & Payment date:

- Commencement and Payment date is the date you sign this agreement.

Increases:

- After three years increases will only reflect any inflationary rises.
- You will always be given 90 days to consider renewing your agreement.
- You will be given the opportunity to accept a further 3 years agreement at the end of this.

Confidentiality & Liability:

- Both parties agree not to disclose any confidential or proprietary information under this agreement to third parties unless required to by law.
- Advice and information provided by MDG is without liability.

Termination & Jurisdiction:

- Either party may terminate the agreement by giving notice in writing to the other party 90 days before the renewal date of this agreement.
- This agreement is subject to the laws of England and Wales.

Acceptance

Signed on behalf of M. Devices Group:

Name: Paul Shane Bennetts Title: Managing Director

Accepted on behalf of:

Signature: _____ Commencement date: _____ 200_

Name: _____ Title: _____

Witnessed by:

Signature: _____

Name: _____ Title: _____

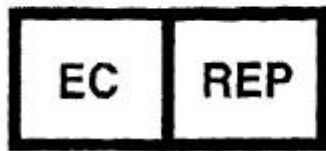


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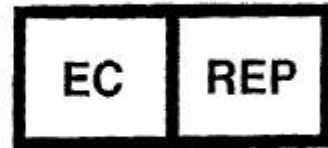
***Annex I**

*** Recommended Symbols:**

A.7 Examples of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"



**Company
Address**



Company