MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
FORM RG2

REGISTRATION OF PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE MARKET

PART 1: *About the notification*

Please read the accompanying guidance notes before commencing.
Please complete in type face or block letters. The form may be copied if required..

1. Enter the date of notification.

Day . Month . Year

COMPETENT AUTHORITY USE ONLY

File Reference Number

Date Received

. .

2. Please indicate if this is the first, further, or change of information.

First	Further	Change

If further or change please provide previous reference number.

Previous Reference Number

CA.....

3. Please indicate the status of the organisation making this registration notification by ticking the appropriate box.

Manufacturer	Authorised Representative	Assembler of System and procedure packs (Regulation 11/ Article 12)	Other

4. The statement opposite must be completed by an authorised signatory of the manufacturer, authorised representative, or other organisation responsible for placing the device(s) on the market. (see guidance notes)..

I, *(please print full name)*

affirm that the information provided in this notification is accurate and that the Class I devices/Custom-made devices/System and procedure packs (Regulation 14/Article 12) (please delete as appropriate) covered by this notification meet the provisions of the Regulations which apply to them.

Signed Date

Position

Company Name

PLEAE SEND COMPLETED FORM TO: REGISTRATION SCHEME OFFICER Medicines & Healthcare products Regulatory Agency, 8th Floor Wing 2, 1 Nine Elms Lane, London, SW8 5NQ

PART 2: *Manufacturer Information*

Tick this box if you are notifying a change of name or address: ☐

5. Enter the full name and postal address of the manufacturer, or person responsible for placing the device(s) on the market if based in the UK. (This relates to the address information on the labelling or packaging).

UK ADDRESS

Manufacturers name or person responsible

Address

*Telephone and facsimile number

Telephone | Facsimile number

MANUFACTURER'S ADDRESS IF OUTSIDE EC

*Enter the full name and postal address of the manufacturer if based outside the EC. (This relates to the address information on the labelling or packaging).

Manufacturers name or person responsible

Address

*Telephone and facsimile number including international codes.

Telephone | Facsimile number

*DENOTES INFORMATION WHICH IS ADDITIONAL TO DIRECTIVE REQUIREMENTS

PART 3: *Device Information*

6. *Enter details of Notified Body approval of quality system for sterilisation or measuring function relevant to the device(s).

Notified Body Identification Number	Covering

CLASS 1 DEVICE(S) COMPLETE 7 OR 7A

7. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate enter your generic name(s) at 7a below.

Generic Code Name(s)				

7a. Enter your generic name(s) of device. More than one group may be registered providing all other information within the form applies.

Generic Name(s)

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED

FOR CUSTOM-MADE DEVICE(S) AND/OR SYSTEM AND PROCEDURE PACKS SEE OVER

CUSTOM-MADE DEVICE(S) COMPLETE 8 OR 8A

8. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate, enter your generic name(s) at 8a below.

Generic Code Name(s)

8a. Enter your generic name(s) of devices. More than one group may be registered providing all the other information within the form applies.

Generic Name(s)

SYSTEM AND PROCEDURE PACKS (REGULATION 14/ARTICLE12) COMPLETE 9 OR 9A

9. Please refer to list of product codes and note generic family group code letter(s). If none appear appropriate enter your generic name(s) at 9a below.

Generic Code Name(s)

9a. Enter your generic name(s) of system or procedure packs. More than one group may be registered providing all the other information within the form applies.

Generic Name(s)

STERILISATION COMPANIES (REGULATION 14/ARTICLE 12)

10. If you are registering because you sterilise devices for which you are not the manufacturer and place them on the market under your own name, please tick the box.

Tick box if applicable ☐

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED

MEDICAL DEVICES REGULATIONS 2002

REGULATION 19: REGISTRATIONS

Class I/Custom-made medical devices & Article 12 Registrations: Instructions on completing Registration form, RG2

*** Please note that registration notifications for In Vitro Diagnostic medical devices (IVD's) should be made using form RG3**

WHEN TO REGISTER:

CLASS I

Only when you first apply the CE marking to your devices in accordance with the
Essential Requirements of the Medical Devices Directive, 93/42/EEC.

CUSTOM MADE/ARTICLE 12

Only when you claim compliance with the Regulations and manufacturer/assemble
devices in accordance with the requirements.

Please note the following, which includes changes to the Regulations:

1. **There is a charge of £70 (inc. VAT) per registration form or change of registration. This fee should accompany the RG2 form when it is sent to MHRA. Please make cheques payable to "Medicines & Healthcare products Regulatory Agency".**

2. **Authorised Representatives must provide evidence that they are acting with the consent of a manufacturer located outside the European Community. This may take the form of a letter of designation from the manufacturer.**

3. **All RG2 forms must bear the original signature of an authorised signatory.**

Guidance on completing Registration form, RG2

This advice note should be read in conjunction with "Guidance Note 8 - Guidance Notes for the Registration of Persons Responsible for Placing Devices on the market" and Appendices A & B.

PART 1.2

- Please tick ‘First’ when notifying MHRA of a registration for the first time **not** for subsequent notifications.

- Please tick ‘Change’ when there is a change to a company name, business address or when product categories are discontinued.

- Please tick ‘Further’ when notifying the MHRA of further generic codes.

- Please quote the CA reference number allocated after the first notification if possible.

PART 1.3

Manufacturer - Person who places a product on the market **in his own name**. This includes persons overlabelling medical devices produced by another party and “own branders”. Please refer to Bulletin 19* for further clarification.

Authorised Representative - Person with an established place of business based within the European Community (EC), acting on behalf of a manufacturer not based within the EC for the registration process. Please note the form RG2 should be completed by the Authorised Representative **not** the non-EC based manufacturer and that only Authorised Representatives based in the UK should register with MHRA.

Assembler of System and procedure packs - Person responsible for putting together a system or procedure pack containing both CE marked and non-CE marked products, in accordance with Article 12 of the Medical Devices Directive.

Other - Use only when none of the above are applicable. Please provide full details of the circumstances in a covering letter.

PART 2

- **Authorised Representatives are asked to complete the whole of page 2.**

SECTION 7/7A

- **Please refer to Appendix B**
  Only the codes listed in appendix B should be used. If you are unsure which codes are applicable please send in adequate product literature and a description of the device to enable us to allocate to an appropriate generic group.

GENERAL GUIDANCE

- The registration fee is per RG2 form not per product. Multiple generic codes may be entered on the same form.

- One generic code can cover several products. There is no requirement to notify MHRA of products falling within a generic code for which you have already registered.

- No refund will be made if MHRA is of the opinion that the products described on the RG2 do not fall within the definition of "medical device" given in the Directive.

- **Opticians** please register under Article 12 for glazing work.

- Please note a Notified Body must be involved when a Class I medical device is sterile or has a measuring function.

* Further regulatory guidance may be obtained from:
European and Regulatory Affairs, Medicines & Healthcare products Regulatory Agency, 8th Floor, 1 Nine Elms Lane, London SW8 5NQ

For further clarification on registrations please see below:

General enquiries: 020 7084 3318

Web-site: www.mhra.gov.uk

Please send completed RG2 forms to:
Registration scheme officer
Medicines & Healthcare products
Regulatory Agency
8th Floor
Wing 2,
1 Nine Elms Lane,
London
SW8 5NQ