



COMPETENT AUTHORITY (UK)

MEDICAL DEVICES REGULATIONS 1994: REGULATION 14 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
.	.	

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

First	Further	Change
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COMPETENT AUTHORITY USE ONLY

File Reference Number

Date Received

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
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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 11 / 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

PART 2: Manufacturer Information

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

UK 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).

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

Address

*Telephone and facsimile number including international codes.

Telephone

Facsimile number

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 I 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)				

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

Generic Name(s)

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PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED

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)				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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)

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SYSTEM AND PROCEDURE PACKS (REGULATION 11 / ARTICLE 12) 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)				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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)

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STERILISATION COMPANIES (REGULATION 11 / 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 <input type="checkbox"/>

PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED