Competent Authority (UK)

Medical Devices Regulations 2002 No. 618, Regulations 19 and 30

Form RG2 – registration of medical devices

For office use only	Date of receipt	

Evidence in support of application checklist					
Authorised representative application Y/N	Designation letter attached Y/N	Applications replacing an existing AR need a cancellation of their contract/agreement from the overseas manufacturer, has the new AR attached it to this registration? Y/N	Details of the device(s) fully provided. Product labelling and instructions for use for custom made active implantable devices ONLY provided Y/N	Legal entity of the business letter attached Y/N	Payment attached Y/N
Further info required documents Y/N		Info / payment/	Proceed with registration Y/N		

PLEASE ONLY COMPLETE THE RELEVANT SECTIONS/BOXES

Part 1: About the registration notification

Please read the accompanying guidance notes prior to completing this form.
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 registration or change of information.
First ☐ Change ☐

If change please provide previous reference number CA

3. 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) ☐
Custom Made Active Implantable Device (please include the instruction for use with the RG2 form) ☐

4. The statement below 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, (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) (delete as appropriate) covered by this notification meet the provisions of the Regulations which apply to them.

Signed _____ Date _____

Position _____
Manager/Owner/CEO, CFO, Proprietor etc

Company Name (if you are placing devices on the UK market under your **personal name** please place this information here)
_____

Part 2: manufacturer information

UK address

5. Enter the full (a) Company/Personal name, (b) postal address of the UK manufacturer, or the UK authorised representative responsible
(The address information should correlate with details on the packaging and labelling for the devices being registered).

(a) **Company/Manufacturer's name**. If you are not using a company name, **the name of the person** responsible for placing the device on the market is required here.

(b) Address (PO Box address in **not** acceptable)

PLEASE NOTE: PO Box, Virtual offices and mail forwarding office addresses are not acceptable – the full postal address of where economic activity is carried out is required we require phone and email contact details and website of manufacturer and or Authorised representative (if one exists)

*Please note in addition to a phone number, a fax/email address is required

Telephone* Fax number* or email*

*You are only required to provide the overseas manufacturers address here, if you are a designated authorised representative (AR)

Manufacturer's address if outside the EU

Place in part (c) Company/Personal name, (d) Postal address for the manufacturer based outside the EU.

(c) Company/Manufacturer's name or person responsible

(d) Address (PO Box address in **not** acceptable)

*Please note in addition to a phone number, a fax/email address is required

(Including international codes)
Telephone* Fax number* or email*

*denotes information which is additional to the requirements of the Directive

Part 3: Payment information

Bank details for payment by bank transfer in pounds sterling or foreign currency
Account name: GBS Re MHRA
Account number: 12314800
Sort code: 08-33-00
Swift code: CITIGB2L
Iban: GB05CITI08330012314800
Branch address:
Citibank N.A.
London Branch
Canary Wharf
London
E14 5LB

Details for making pre-payments to the MHRA using a debit or credit card via our online payment system is located under the following webpage;
http://www.mhra.gov.uk/Aboutus/MakeapaymenttotheMHRA/Debitorcreditcardform/index.htm

Payment method - cheque, credit card, or BACS/CHAPS	Payment ref number (only required for BACS/CHAPS or credit card payments)	Date BACS/CHAPS or credit card payment made

Important note
Registrations submitted and paid via credit/debit card or BACS/CHAPS a copy of the print out or the online verification reference information/page should be provided with the registration form(s).

Part 4: device information

6. *Enter details of notified body approval of quality system for sterilization or measuring function (if relevant to your application)

Notified body identification number: Covering:

*denotes information which is additional to the requirements of the Directive

Details of the generic codes to use in parts 7, 8 and 9 are given in the guidance part of this form.

Class I Devices 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.

Place generic device code (s) here e.g. H5				

7a. ONLY Enter your generic name(s) of device, **if you are unable to locate a suitable generic code**. More than one group may be registered providing all other information within the form applies.

Generic description of device here

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.

Place generic device code (s) here e.g. K1

8a. Enter your generic name(s) of devices **if you are unable to locate a suitable generic code**. More than one group may be registered providing all the other information within the form applies.

Generic description of device here

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.

Place generic device code (s) here e.g. L5

9a. Enter your generic name(s) of system or procedure packs **if you are unable to locate a suitable generic code**. More than one group may be registered providing all the other information within the form applies.

Sterilization companies (Regulation 14/article 12)

Generic description of device here

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

Send the completed form to:

Registration Scheme Officer
European and Regulatory Affairs (ERA2)
MHRA
Floor 4 yellow zone
151 Buckingham Palace Road
London
SW1W 9SZ

Or via email to: device.registrations@mhra.gsi.gov.uk

Guidance on completing registration form RG2

General guidance

- The registration fee is per RG2 form and not per product. Multiple generic codes may be entered on the same form. You may make additional copies for the devices you wish to register when you run out of room.
- 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.
- A notified body must be involved when a class I medical device is sterile or has a measuring function.

Contact us by telephone under the relevant alphabetical split for the **company name** used for your registration: **A-D** 020 3080 7195 **E-M** 020 3080 7318 **N-Z** 020 3080 7149
Email: mb-mda-era@mhra.gsi.gov.uk

Part 1.2

- Date of registration is the date the form was completed.
- Tick 'First' when notifying the MHRA of a registration for the first time.
- Tick 'Change' when there is a change to the registration details held for example;
- change of company name (including becoming a limited company), change of UK and/or overseas company address, authorised representative, additional product categories and/or when product categories are discontinued.
- (If the change is a change of company name so we may determine whether a change of registration number is appropriate. Please state in writing whether there as or as not been a change to the legal entity of the business and whether the change is just a change of company name).
- 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 over-labelling medical devices produced by another party and 'own branders'. Please refer to our website for clarification.

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

Assembler of system and procedure packs - Person responsible for putting together a system or procedure pack containing both CE marked and Devices Directive.

Part 1.4
The declaration must be signed by or on behalf of the manufacturer, if based in the UK. In the case of the manufacturer being based outside the UK, the declaration must be signed by or on behalf of the authorised representative. In signing the form please note:

that the authorised representative should provide evidence of their status. This may take the form of a contract or headed letter of designation from the overseas manufacturer whom they represent, which should state the AR's full name and address and that they are their designated UK authorised representative under the Medical Devices Directive 93/42EC

Part 2
Part 2 a and b should be completed by persons responsible for placing devices on the UK market, whose registered place of business is based within the UK. Registrations submitted by an UK authorised representative should place their address in Part 2 a and b and the overseas company details in Part 2 c and d.

Part 3
Payment Information – If you have submitted a payment via BACS, CHAPS, credit card or debit card, you will need to fully complete this section and **attach a copy of the payment transaction receipt** Please note under Regulation 53 of the Medical Devices Regulations 2002 No. 618 it is a statutory obligation to provide the payment at the time of submitting the registration/notification. Additionally, providing the payment together with the form will allow us to process your registration in a timely manner.

Please note the fee applies to change of company name (including becoming a limited company), address, additional devices to be added to an existing registration and change of authorised representative. A statutory fee does not apply if the change is any of the following: Removal/discontinuation of devices, change of contact person, change of postcode and/or change of phone number. These changes should be noted in writing via email or hardcopy.

Section 7/7a, 8/8a and/or 9/9a
You may use the MHRA list of generic description codes (provided below) or the nomenclareture called The Global Medical Device Nomenclature (GMDN) which can be obtained via their website http://www.gmdnagency.com. Please note a membership license fee applies to enable access and the use of GMDN codes, information on this can be viewed on the GMDN Agency website.

Note: If you are unable to assign an appropriate product code for a device and you wish to register with the UK competent authority, please enter a brief description of the device(s), its intended use, and mode of action in **Section 7a, 8a, or 9a** of the registration form RG2. It may also help us, if a picture or technical diagram of the device is also provided, in addition to the completed registration form. Please also provide a general/generic description name for the product(s) you wish to register. You should avoid specific brand names or devices types as any changes to the registration details held incurs payment of our statutory fee.

Note: the MHRA will **not** accept a product catalogue/brochure as a means of application for registration. The manufacturer should complete and sign the notification of registration form RG2.

MHRA generic device codes for class I, custom made and/or systems and procedure packs

These lists are for guidance only and there are likely to be many more devices than those listed here.

The inclusion of a device category on this list is not a statement that it necessarily falls within class I, custom made and/or systems and procedure packs. The risk classification of a product will vary depending on the claims made for it, and the materials it contains. Manufacturers should review the classification of their products on a case by case basis in accordance with the rules set out in Annex IX of the Medical Devices Directive 93/42EEC.

Class I (see section 7/7a)

Administration

A 1 Measuring and mixing devices for medicines
A 2 Inhalation devices (e.g. chamber spacers)
A 3 Sets - solution/irrigation (gravity only)
A 4 Syringes (hypodermic / oral / irrigation)
A 5 Dispensers (cement, etc.) and accessories
A 6 Sensitivity testing devices
A 7 Non-active auto injector devices
A 8 Non-active infusion devices and accessories

Dental

B 1 Dental lights
B 2 Dental diagnostic fibre optic hand pieces
B 3 Dental instruments (reusable and non-powered)
B 4 Dental prophylaxis paste (non-fluoride)
B 5 Handheld dental mirrors and accessories
B 6 Impression materials, trays and adhesives / bite wafers
B 7 Orthodontic materials (extra-oral / intra-oral transient and short-term use)
B 8 Retraction cords/dental wedges/rubber dam/matrix bands
B 9 Articulating paper/spray
B 10 Waxes
B 11 Dental unit accessories
B 12 Artificial teeth
B 13 Base materials
B 14 Dental mouthwash tablets (non-medicated)
B 15 Denture lining materials/adhesives
Z 169 Denture cleaning liquids/tablets (non-disinfecting)(dental devices)
Z195 Dental brace/denture fitting aid (dental devices)
Z 275 Denture cleaning brushes (dental devices)

Diagnostic

C 1 Conductive gels
C 2 Electrodes/transducers and accessories
C 3 Peak flow meters
C 4 Sphygmomanometers and accessories
C 5 Stethoscopes
C 6 Thermometers (clinical)
C 7 Examination/procedure gloves
C 8 Blood sampling devices (re-usable)
C 9 Endoscopes/endoscopic instruments and accessories
C 10 Image storage and retrieval system
C 11 Laryngoscopes / otoscopes and accessories
C 12 X-ray cassettes, cassette holders, image enhancers and intensifying screens
C 13 Radiographic film processing chemicals
C 14 X-ray film illuminators
C 15 Sampling and cell collection devices (patient contact - not IVDs)
Z 102 Audiometer accessories (electro-medical mechanical devices)
Z 202 X-ray film markers and accessories (diagnostic and therapeutic radiation devices)
Z 203 Patient radiation protection products and accessories (diagnostic and therapeutic radiation devices)

Dressings

D 1 Bandages (e.g. support / tubular / adhesive / plaster of paris / cast liners / resin)
D 2 Cotton wool/gauze / non woven (ribbons / swab / buds)
D 3 Adhesive plasters / dressings / tapes / barrier films
D 4 Eye occlusion plasters/shields and corneal shields
D 5 Chiropody dressings and pads
O 8 Wound manager (single-use)

Equipment and furnishings

E 1 Allergen resistant bedding
E 2 Examination / treatment couches and leg / arm rests

E 3 Hospital beds and patient positioning aids
E 4 Patient hoists / transfer aids and accessories
E 5 Pressure relief devices and accessories
E 6 Treatment chairs (chiropody/dental / ophthalmic)
E 7 Stretchers / chairs / hospital trolleys (patient transport)
E 8 Traction and surgical immobilisation devices
E 9 Medical examination luminaries
E 10 Rehabilitation equipment
E 11 Splints (limb / body / ear) / collars
E 12 Resuscitation devices (non-active) and accessories
E 13 Warming and cooling pads and blankets (non-active and non-chemical)
O 7 Speech / breathing training devices (technical aids for disabled persons)
Z 50 Cleaner/ washer for medical devices (hospital hardware)
Z 125 Ultrasonic cleaners and solutions (hospital hardware)
Z 131 Surgical equipment sterile drapes (hospital hardware)
Z 135 Autoclave accessories (e.g. trays and tray lifters, shelves, racks) (hospital hardware)
Z 143 Speech synthesisers / communication aids / voice amplification systems (technical aids for disabled persons)
Z 154 Tourniquets and tourniquet machines (electro-medical mechanical devices)
Z170 Instrument cleaning solutions / wipes (non-disinfecting) (hospital hardware)

Ophthalmic

F 1 Lamps (ophthalmic examination)
F 2 Fundas cameras / keratometers / slit lamp microscopes and associated software
F 3 Low vision aids
F 4 Operating room microscopes / magnification systems
F 5 Ophthalmoscopes / retinascopes
F 6 Spectacle lenses
F 7 Spectacle frames
F 8 Ready-made spectacles (non-prescribed)
F 9 Sight testing devices
O 9 Schirmer tear test (sterile product) (ophthalmic and optical devices)
Z 45 Class I tonometer (reusable)
Z 105 Eye specula (ophthalmic and optical devices)
Z130 Contact lens accessories (ophthalmic and optical devices)
Z 148 Eye Baths/irrigation systems and eyewash solutions (ophthalmic and optical devices)

Orthoses and prostheses

G 1 Orthopaedic footwear
G 2 Orthoses (lower and upper limb/spinal/abdominal/neck/head)
G 3 Trusses
G 4 Compression hosiery/garments
G 5 External limb prostheses and accessories
G 6 Stump socks and boards
G 7 Orthopaedic casting/support products and accessories
Z176 Postural support products (technical aids for disabled persons)

Surgical

H 1 Umbilical clamps/tape
H 2 Tubes (oesophageal/rectal) and accessories
H 3 Enema and douche devices
H 4 Incision drapes/theatre clothing

H 5 Surgical instruments (reusable and non-powered)
H 6 Pre-operative devices (razor/marker pen)
H 7 Airway devices/monitoring equipment and accessories
H 8 Non-invasive drainage devices and accessories
H 9 Surgical instrument accessories
H 10 Sterilization packaging
H 11 Accessories for implantable devices (non-invasive)
H 12 Operating tables and accessories
Z 116 Vaginal specula (reusable devices)
Z 136 Electrosurgical accessories (e.g. transient invasive electrodes, footswitches) (electro-medical mechanical devices)

Walking aids and wheelchairs

I 1 Crutch/walking stick
I 2 Walking frame/multi-leg walking aid/standing frame
I 3 Rollator/ mobilator
I 4 Wheelchairs (non-powered) and accessories
I 5 Wheelchairs (powered) and accessories
I 6 Mobility aids for the visually impaired
Z168 Rehabilitation tricycles/mobility carts (technical aids for disabled persons)

Waste collection

J 1 Ostomy collection devices and accessories
J 2 Incontinence pads and accessories
J 3 Urinary bags and accessories
J 4 Non-invasive tubing (waste disposal)
J 5 Penile sheaths
J 6 Urinary catheters (transient use) and accessories

Other

Z 48 Telemedicine accessories (reusable)
Z 129 Acupressure devices
Z 146 Head lice devices (reusable)
Z 147 Dilators and lubricants (reusable)
Z 162 Nasal speculum (reusable)
Z 218 Lubricants (instruments/electrode pads) (single-use)
Z 301 Standalone Software

Custom-made devices (see section 8/8a)

K1 Dental appliances/prostheses
K2 Hearing aid inserts
K3 Prescribed orthopaedic footwear
K4 Artificial eyes
K5 Orthoses and prostheses - external (made direct from casts/prescriptions)
K6 Orthopaedic implants
K7 Maxillo-facial devices
K8 Standing and walking frames
K9 Ligament and tendon repair implants
K10 Spectacle frames
Y4 Mandibular advancement device (anaesthetic and respiratory devices)

Y10 Insoles (made direct from casts) (technical aids for disabled persons)
Y13 Postural support products (technical aids for disabled persons)
Y15 Splints (limb/body/ear)/collars (single use)

System and procedure packs (article 12) (see section 9/9a)

L1 Ward dressing packs
L2 Theatre dressing packs
L3 Oral hygiene packs
L4 First aid kits
L5 Prescribed spectacles
L6 Cerebrospinal fluid filter with syringe
L7 Ophthalmic surgical procedure packs
L8 Orthodontic procedure packs
L9 Skin traction kits
L10 Surgical procedure packs (includes instruments supplied singularly)
X5 Theatre drape packs (single use)
X6 Needle exchange packs (single use)
X11 Endoscopes/endoscopic instruments and accessories (electro-medical mechanical devices)
X14 Orthoses and prostheses procedure packs (single use)
X18 Blood specimen collection kits (single use)

Important note
Once the form and payment have been submitted to us there is no requirement for companies to wait for an acknowledgement letter from the MHRA before placing CE marked devices on the EU market. As the registration process is a self declaration process whereby manufacturers and their authorised representatives determine that the device(s) fall within the definition of 'medical device' or 'in vitro diagnostic medical device', and that they have classified them as falling within Regulation 19 /44 of the Medical Devices Regulations 2002 No. 618 taking into account the intended purpose(s) and mode(s) of action. In accepting a registration, the competent authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does the MHRA's registration letter represent any form of accreditation, certification or approval by the UK competent authority. The MHRA does, however, reserve the right to take action against products placed on the UK market which are considered to be incorrectly CE marked as medical devices or incorrectly classified.

Further regulatory guidance may be obtained from our website: www.mhra.gov.uk

Email address: mb-mda-era@mhra.gsi.gov.uk, or you may contact us by phone under the relevant alphabetical split for the company name:
A – D 020 3080 7195

E – M 020 3080 7318

N – Z 020 3080 7149

In line with the requirements of the Hampton Report on Reducing Administrative Burdens - Effective Inspections and Enforcement, MHRA keeps its guidance documents under constant review. If you have any feedback, particularly on the presentation, accessibility or clarity of any of our guidance notes or bulletins could you please inform us using the contact details provided.