



COMPETENT AUTHORITY (UK)

IN VITRO DIAGNOSTIC MEDICAL DEVICE REGULATIONS 13 & 14 FORM RG3

PART 1: Identification of the registration

6200	Date of notification		<input type="checkbox"/> Is the relevant fee enclosed?
6220	Please indicate if this is a: <input type="checkbox"/> first notification (<i>please complete all parts of the form</i>) <input type="checkbox"/> change of address (<i>please complete parts 2 and/or 3 only</i>) <input type="checkbox"/> discontinuation of product by manufacturer/authorised representative <input type="checkbox"/> change of product or group of products		
6230	If change or discontinuation please provide previous registration reference number		
6240	Status of the organisation making this notification: <input type="checkbox"/> Manufacturer (<i>please fill in Part 2</i>) <input type="checkbox"/> Authorised representative (<i>please fill in Parts 2* & 3 - if you are an authorised representative, you must supply sufficient evidence that you are the authorised representative of the manufacturer, eg a letter of designation</i>)		

PART 2: Identification of the manufacturer

6260	Manufacturer's name (<i>this relates to the information on the labelling of the devices</i>)		
6310	Street	6300	Post Code
6290	City		Country
6320	Contact name*	6350	E-mail*
6330	Telephone*	6340	Fax*

PART 3: Identification of the authorised representative

6380	Authorised Representative's name (<i>this relates to the information on the labelling of the devices</i>)		
6396	Street	6394	Post Code
6392	City	6398	PO Box*
6400	Contact name*	6430	E-mail*
6410	Telephone*	6420	Fax*

PART 4:Declaration

I affirm that the information provided in this notification is accurate and that the devices (listed in Parts 5 and 6) covered by this notification meet the provisions of the Regulations which apply to them.

- Additionally for authorised representatives, that I have provided evidence that I am the authorised representative of the manufacturer of the relevant device being placed on the market.
- If devices are listed in Annex II or self-testing that I have kept available:
 - data relating to analytical and where appropriate diagnostic parameters as referred to in Section 3 of Part A of Annex 1
 - labelling and instructions for use
 - outcome of performance evaluation pursuant to Annex VIII
 - relevant certificates
- If the devices are for performance evaluation that I have met the requirements of Annex VIII

This notification comprises ____pages (please insert how many pages you are sending)

Signature _____

Name _____

Position _____

Company _____

Date _____

*Please send the completed form to the Registration Scheme Officer, European and Regulatory Affairs,
Medical Devices Agency, Hannibal House, London SE1 6TQ*

***For devices listed in Annex II and self-testing devices, fill in Part 6 .
For all except those devices listed in Annex II or self-testing devices, fill in Part 5***

PART 5: IVD's which are not Annex II and not self test devices

Please copy this page as necessary so that new products and performance evaluations are listed on separate pages from each other and those which are neither. Please also keep discontinued products separate from other notifications. See attached nomenclature leaflet for generic device group codes.

6445	Are the devices listed on this page: <input type="checkbox"/> "New" products? <input type="checkbox"/> For performance evaluation? <input type="checkbox"/> Neither? <input type="checkbox"/> Discontinuation of any of the above?
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For reagents, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

6450	Nomenclature system used	GMDN? <input type="checkbox"/>	EDMS? <input type="checkbox"/>
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6465 Group Code	Group name (Common Technological Characteristic and/or analyte) <i>If none appear appropriate from the chosen nomenclature enter short description(s) into 6490 below</i>

6490	Short description(s) (only use if no generic group code exists) - please continue on a blank sheet if additional space required.
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For other IVDs, group by appropriate indications (i.e. not reagents, reagent products, calibration and control materials)

6550	Nomenclature system used	GMDN? <input type="checkbox"/>	EDMS? <input type="checkbox"/>
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6565 Group Code	Group name (appropriate indications)) <i>If none appear appropriate from the chosen nomenclature enter short description(s) into 6590 below</i>

6590	Short description(s) (only use if no generic group code exists) - please continue on a blank sheet if additional space required.
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PART 6: IVDs which are Annex II or self-test devices

(Each product introduced or discontinued must be individually notified, one device per page; please copy if additional pages are required)

6605	Product name
6440	Is the device: List A? <input type="checkbox"/> List B? <input type="checkbox"/> Self-test? <input type="checkbox"/>
6445	Is the device: New product? <input type="checkbox"/> For performance evaluation? <input type="checkbox"/> Neither? <input type="checkbox"/> Discontinuation of any of the above? <input type="checkbox"/>
6610	Conformity assessed by Notified Body? <input type="checkbox"/> 6615 NB ID number
6620	If Annex II List A, does it conform to the CTS? If not, please indicate how the manufacturer demonstrated compliance with the Essential Requirements? (<i>Give reference of CTS or equivalent test method used</i>)

For reagents, reagents products, calibration and control materials: group by common technological characteristics and/or analytes

6450	Nomenclature system used GMDN? <input type="checkbox"/> EDMS? <input type="checkbox"/>
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6465 Group Code	Group name (Common Technological Characteristic and/or analyte) <i>If none appear appropriate from the chosen nomenclature enter short description(s) into 6490 below</i>

6490	Short description (<i>use only if no generic group code exists</i>)
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**For other IVDs, group by appropriate indications
(i.e. not reagents, reagent products, calibration and control materials)**

6550	Nomenclature system used GMDN? <input type="checkbox"/> EDMS? <input type="checkbox"/>
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6565 Group Code	Group name (appropriate indications <i>If none appear appropriate from the chosen nomenclature enter short description(s) into 6590 below</i>)

6590	Short description (<i>use only if no generic group code exists</i>)
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