



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="text" value="30 OCT 2003"/>	<input checked="" type="checkbox"/> Is the relevant fee enclosed?
6220	Please indicate if this is a: <input checked="" 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 checked="" type="checkbox"/> Authorised representative ( <i>please fill in Parts 2* &amp; 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> ) <input type="text" value="Respiratory Research, Inc."/>		
6310	Street	<input type="text" value="1167 Raintree Drive"/>	6300 Post Code <input type="text" value="22901"/>
6290	City	<input type="text" value="Charlottesville, Virginia"/>	Country <input type="text" value="USA"/>
6320	Contact name*	<input type="text" value="John Hunt"/>	6350 E-mail* <input type="text" value="jhunt@respiratoryresearch.com"/>
6330	Telephone*	<input type="text" value="001 434 825-0074"/>	6340 Fax* <input type="text" value="001 434 431 2613"/>

## 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> ) <input type="text" value="Indoor Biotechnologies, LTD"/>		
6396	Street	<input type="text" value="The Quadrant Center&lt;br/&gt;Cardiff Business Park"/>	6394 Post Code <input type="text" value="CF14 5WF"/>
6392	City	<input type="text" value="Cardiff"/>	6398 PO Box*
6400	Contact name*	<input type="text" value="Lyn Williams"/>	6430 E-mail* <input type="text" value="lynwilliams@indoorbiotech.co.uk"/>
6410	Telephone*	<input type="text" value="029 2076 1177"/>	6420 Fax* <input type="text" value="029 2076 5523"/>

## **PART 4:Declaration**

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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 checked="" 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 checked="" 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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**Exhaled breath condensate collector and sample storage**  
 RTube and pHTube collect (under MDD) and store (under IVDD) samples of condensed breath

## 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"/> <span style="background-color: #cccccc; padding: 2px;">6615</span> 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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