

## 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
10	30	2003

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

First	Further	Change
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

COMPETENT AUTHORITY USE ONLY
File Reference Number
Date Received
. .

If further or change please provide previous reference number.

Previous Reference Number	CA.....
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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
	<input checked="" type="checkbox"/>		

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)* Lyn Williams

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 30 OCT 2003

Position International Business Manager

Company Name Indoor Biotechnologies, LTD

## 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).

Please note: Indoor Biotechnologies is the Authorized Representative in the UK for Respiratory Research, Inc.

### UK ADDRESS

Manufacturers name or person responsible

Indoor Biotechnologies, LTD

Address

The Quadrant Centre  
Cardiff Business Park  
Cardiff CF14 5WF  
United Kingdom

\*Telephone and facsimile number

Telephone

+44 (0) 29 2076 1177

Facsimile number

+44 (0) 29 2076 5523

\*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).

### MANUFACTURER'S ADDRESS IF OUTSIDE EC

Manufacturers name or person responsible

Respiratory Research, Inc.

Address

1167 Raintree Drive  
Charlottesville, VA 22901  
USA

\*Telephone and facsimile number including international codes.

Telephone

++1 434 825-7627

Facsimile number

++1 434 431 2613

**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
<input type="text" value="n/a"/>	

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.

**CLASS 1 DEVICE(S) COMPLETE 7 OR 7A**

Generic Code Name(s)				
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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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)
<input type="text" value="Exhaled Breath Condensate collection system (RTube and pHTube)"/>

Please note- Our devices are simple collectors of exhaled breath condensate. A mouthpiece (similar to clarinet mouthpiece) is used to exhale through, and the mist is collected from the exhaled breath for later laboratory analysis. There is no measuring function. Just collection and storage.

<input type="text"/>
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<input type="text"/>
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<input type="text"/>
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PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED

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

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.

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

Generic Code Name(s)

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

9. Please refer to list of product codes and note generic family group code letter(s). If non appear appropriate enter your generic name(s) at 9a below.

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

Generic Code Name(s)

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

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.

**STERILISATION COMPANIES (REGULATION 14/ARTICLE 12)**

Tick box if applicable

**PLEASE COPY IF ADDITIONAL PAGES ARE REQUIRED**