



## **GROUP CODES FOR IVD REGISTRATION**

**The Medical Devices Regulations 2002: Regulation 44: Form RG3**

**To be read in conjunction with MHRA publication "Guidance Notes for the Registration of Persons Responsible for Placing in vitro Diagnostic Devices on the Market "**

### **THE EDMA IVD PRODUCT CLASSIFICATION SYSTEM**

The Regulations require manufacturers and authorised representatives based in the UK to register with the Medicines & Healthcare products Regulatory Agency details of themselves and the IVDs they are placing on the market.

The devices are required to be grouped together for registration purposes, and this document describes how to complete the relevant parts of the MHRA registration form RG3. Guidance on all other aspects of RG3 can be found in the MHRA booklet "Guidance Notes for the Registration of Persons Responsible for Placing in vitro Diagnostic Devices on the Market", available from MHRA at the address below.

Standardised groupings are required in order to facilitate the entry of, and access to, the registration data in the European database. Therefore each device grouping has a numerical Group Code so that the groupings can be entered and accessed in a systematic and consistent manner which is independent of language.

It is intended by Member States that groupings from the Global Medical Devices Nomenclature System be used when available. In the interim, the system generated by the European Diagnostic Manufacturers Association (EDMA) is to be used and copies of the relevant parts are attached. The full system may be downloaded from EDMA Web-Site at <http://www.edma-ivd.be/>.

**Further guidance may be obtained from:**

**Medicines & Healthcare products Regulatory Agency, Market Towers  
8<sup>th</sup> Floor, 1 Nine Elms Lane, London SW8 5NQ**

**Telephone: 020 7084 3318**

**Web-site: [www.mhra.gov.uk](http://www.mhra.gov.uk)**

## Completion of RG3: Parts 5 and 6

Please note these questions are common to both Parts 5 & 6 of RG3

<b>Questions 6450 and 6550</b>	<b>Mark “EDMS”</b>
<b>Nomenclature system used</b>	
<b>Question 6465: Group Code</b>	<p>For reagents, reagent products, calibration and control materials, you should identify the relevant analyte for each product, or group of products, which you wish to register and enter its 8 digit code.</p> <p>Alongside each group code, please enter the name of the corresponding analyte as listed in the “Reagent Classification” pages of the EDMA system. This will enable us to check on the validity of the code you have chosen when we transcribe it into MHRA’s database and subsequently transfer it to the European database.</p>
<b>Question 6490: Short description</b>	<p>If you cannot find the relevant analyte listed for any of your devices, please enter a short description here.</p>
<b>Question 6565: Group Code</b>	<p>For other IVDs, you should identify the relevant indication from the “Instrument Classification Overview” pages of the EDMA system for each product, or group of products (including accessories), you wish to register and enter its 6 digit code.</p> <p>Alongside each group code, please enter the name of the corresponding instrument grouping. This will enable us to check on the validity of the code you have chosen when we transcribe it into MHRA’s database and subsequently transfer it to the European database.</p>
<b>Question 6590: Short description</b>	<p>If you cannot find the relevant type of instrument listed for any of your devices, please enter a short description here.</p>

**For Part 5**, please continue until you have entered all the analyte or instrument groupings covered by the devices which you wish to register, photocopying the relevant blank page of the RG3 form if necessary.

**For Part 6**, each individual product should be notified separately, together with its relevant grouping, photocopying Part 6 so that each product is notified on a separate sheet.