Guidelines for completing the IVD registration form and the procedure for notification

General remarks

All CE marked in vitro diagnostic products; according to the IVD directive 98/79/EC shall be either registered or notified with the Competent Authority (CA-SE) before being placed on the Swedish market. (This rule is applicable until the European Databank on IVDs is established).

As of September 1st, 2001 the Unit for Medical Device Technology has been relocated to Medical Products Agency (mpa), hence the national regulations has been converted to LVFS 2001:7.

To clarify the level of registration/notification the following description may be useful: "A product aimed for the diagnostic market is normally identified by a unique article number (or corresponding alphanumeric code) and corresponds to one row in a price list".

Manufacturer or an authorised representative with a registered place of business in Sweden shall register all products made available on the Swedish market with (CA-SE). The Swedish registration form contains the required information to be transferred to the forthcoming database. (EUDAMED in progress)

NOTE! Manufacturers or authorised representatives who are based outside Sweden and are placing CE marked products on the Swedish market shall notify the Competent Authority (SE) by sending a copy of the applicable form filed and accepted by any other Member State. This notification will be acknowledged for placing the product on the Swedish market but not registered with an issued certificate of registration.

Registration procedure

The manufacturer/authorised representative shall complete one form for each product or product group classified for a given analyt i.e. products with the same EDMA code.
The form is compressed to one page divided in four (4) sections. The e-format is expandable when entering product variants under a common analyt number (EDMA-code) or upon added explanatory text to the included fields. Each data field is limited to the number of characters used in the Swedish database. The \texttt{<TAB>\langle shift\rangle<TAB> function will guide you through the form.}

A paper copy of the document shall be signed and sent to the address stated below. To simplify the registration a short product information e.g. a pamphlet or folder and an electronic copy (diskette or CD) of the application form may be appended.

**Comments to the respective sections in the form.**

*Manufacturer and Authorised representative sections:*

Indicate if the application concerns a new (first) registration of the company or any change of already filed information. If the application includes changes, please give the number of the previous registration certificate issued by CA-SE. The company name and address shall be identical to the information given on the labelling used on the Swedish market. State the country specific organisation or ID number for the company. Indicate the contact point, this to enhance future communication.

*Product identification section:*

Indicate if the application concerns a new (first) registration of the product. If the application concerns a withdrawal or any change of already filed information, give the registration number of the previous application issued by CA-SE.

State the product name (trade name) as used on the Swedish market together with a unique article/catalogue number or equal and give a short description indicating the intended use and function of the product. For a, by definition, "NEW" product expand the description to indicate the new concept/functionality introduced by the product. Indicate the product belonging as Common or Specified (Annex IIA/B or Selftest). For specified products, state the identification number for the Notified Body in connection with the issued certificate number.

Classify according to the EDMA nomenclature pending finalisation of the GMDN system. Products with identical 8 digit EDMA code can be reported on the same form (i.e. items related to
the determination of a given analyt). 

**Declaration section:**

The registration signed by a person with an authorised responsibility for the product(s) shall be sent to:

Medical Products Agency  
Department of Medical Devices  
SE-751 03 UPPSALA  
Sweden

Questions may be forwarded to the

Department of Medical Devices

registrator@mpa.se

Telephone: +46 18 17 46 00

Fax: +46 18 50 31 15