Legislation on In vitro diagnostic devices

The European directive on in vitro diagnostic devices (98/79/EC) is implemented into Swedish legislation in the following way.

The Law (SFS 1993:584) and the Ordinance (SFS 1993:876 amended SFS 2001:552) on medical devices includes definitions and regulations. This part of the legislation has been in force since 1993. The IVD directive was published as a national regulation on June 7th 2000. After this date CE marked in vitro diagnostic devices may be put on the market. However, non CE marked in vitro diagnostic devices that conforms with the rules in force December 12th 1998 may be put on the market until the end of the transitional period December 7th 2003. From this day on all in vitro diagnostic products that are placed on the Swedish market must bear a CE mark and consequently be registered in any Member State.

In Sweden registrations are handled by the Unit for Medical Device Technology that on September 1st, 2001 was relocated to Medical Products Agency (mpa), hence the national regulations have been converted to LVFS 2001:7.

Placing a CE marked in vitro diagnostic device on the Swedish market

When placing a CE marked in vitro diagnostic device on the Swedish market the following shall be observed:

Manufacturer or an authorised representative with a registered place of business in Sweden shall register all products made available on the Swedish market with the competent authority, that is the Medical Products Agency in Sweden.

The Swedish registration form, available only in Swedish, contains the required information to be transferred to the forthcoming database. (EUDAMED in progress).

Language

Information to be provided by the manufacturer (see directive 98/79/EC Annex I part B section 8) shall be in Swedish when the device reaches the final user. Special attention shall be given to the instructions for use (IFU), relevant instructions for the operator to handle the procedure from sample preparation to the final readout of the result. For products listed in Annex II and Selftest products, a copy of such IFU will facilitate the registration/notification. These products should also be documented with a copy of the certificate issued from the Notified Body.

Annual registration fee

Specified by the government in the Ordinance (SFS 1993:876 amended SFS 2001:552) on medical devices. The annual fees shall be paid after receiving an invoice from Medical Products Agency.

<table>
<thead>
<tr>
<th>Description</th>
<th>SEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration of one manufacturer/</td>
<td>2.150</td>
</tr>
<tr>
<td>authorised representative</td>
<td></td>
</tr>
<tr>
<td>Registration of 1–10 products</td>
<td>1.000</td>
</tr>
<tr>
<td>Registration of 11–100 products</td>
<td>2.000</td>
</tr>
<tr>
<td>Registration of 101–500 products</td>
<td>5.000</td>
</tr>
<tr>
<td>Registration of more than 500 products</td>
<td>10.000</td>
</tr>
</tbody>
</table>

Certificate of registration

As a confirmation the manufacturer/authorised representative will receive a certificate of registration for each registered product.

NOTE! Notifications as mentioned above are not linked to any fee or certificate. This temporary handling of IVD products registered in any other Member State will be discontinued in connection with the establishment of the European database.

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

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)

**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 application form is available in Word format, in Swedish. 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 <TAB>/<shift><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.

---

**Application form**

- [Registration form - IVD products (in Swedish)]
- [Guidelines for completing the IVD registration form]

**Related information**

- [LVFS 2001:7 (in Swedish)]

**External links**

- [Law: SFS 1993:584 (in Swedish)]
- [Directive 98/79/EC]