ANNEX B

Labelling examples

Introduction

The following set of examples is provided in support of the EMIG position on "Own Brand Labelling".

In the following examples the term "manufacturer" or "manufactured by" are used according to the definition given in the EC Medical Devices Directives. In this definition the "manufacturer" is the person who legally takes the responsibility for the design and manufacture of the device (whether or not he carries out the work himself or directs someone else to do it for him) and who places the product on the market under his own name. The company, which physically makes the device, may or may not be the "manufacturer" depending on whether it is responsible for specifying the overall design and manufacturing process. If this company does not take such legal responsibility for the device it may nevertheless act as a subcontractor of another company which does have overall legal responsibility for the device and is therefore the "manufacturer".

It must be remembered that, although the initial evidence on who is the manufacturer is given on the name and address which appear on the device the real decision on who is the manufacturer must be taken only after a careful assessment of who has the legal responsibility for the product. This is obviously the case where the name and addresses of a company have been wrongly affixed either by simple mistake of by clear intentional fraud.

Finally, it must also be remembered that the EC Declaration of Conformity can only be signed and held by the legal manufacturer.

Example 1

On the device product there is only one name and address of a company (company A) located within the EEA (see FIGURE 1).
In this example company A is the organisation, which takes the legal responsibility for the product in light of the EC Directives.

Possible cases under this example:

1. Company A physically makes the product (in its own facilities).

2. The product is physically made by company B which acts as subcontractor for company A. In this example company B's name and address does not appear on the device (it is not a legal requirement). Company B can be located anywhere in the world.

3. The device can also be distributed by a third company (ies) (C) which name and address need not appear on the product or labelling (not a legal requirement).

In this example, where there is only one name and address on the device it is superfluous to add the word "manufacturer" before the name and address; it is obvious.

Example 2

The device is manufactured by company A (located within the EEA) which, for a number of reasons, wants to rely on company B (also located within the EEA) for sales and distribution in the EEA. The companies have a choice.

Company B make take legal responsibility (EXAMPLE 1) with Company A as subcontractor. Alternatively, Company A may take legal responsibility and be the legal manufacturer, using company B as a distributor.

In the latter case the only name and address which must appear on the device is that of company A.

Provided that company A's name and address appears clearly identified as the "manufacturer" the device get up can be one of the following:

1. The device can have the company A logo, name and colours. The name and address of the distributor (company B) may or may not appear (it is not a legal requirement). If the distributor's name and address does not appear EXAMPLE 1 applies. FIGURE 2 illustrates the position where the distributor's name and address appears.
2. The device can have the company B logo, name, address and colours (see FIGURE 3).

EXAMPLE 3

The device is manufactured by company A (located outside the EEA) directly or though a subcontracted organisation(s). Company A, for a number of reasons, wants to rely on company B (located within the EEA) for sales and distribution in EEA. Unless company A agrees to act as "subcontractor" to company B (see EXAMPLE 1) company A needs to take the legal responsibility for the device and be legal manufacturer.

In this case, in addition to the name and address of company A, there is the obligation to have also the name and address of the authorised representative or importer, which must be located within the EEA.

Provided that company's A name and address is identified as the "manufacturer" and that the name and address of the authorised representative or importer appears clearly the device get up can be one of the following:

1. The device can have the company A (manufacturer) logo, and colours (see FIGURE 4).
2. The device can have the company B (distributor) logo, name, address and colours (see FIGURE 5). The authorised representative or importer can be a different organisation than company B, which acts as a distributor.

Example 1:

Manufacturer	Company A	Address inside EEA	Legal obligation

Example 2:

Manufacturer	Company A	Address inside EEA	Legal obligation
Distributor	Company B	Address inside EEA	Optional

Example 3:

Manufacturer	Company A	Name and Address outside EEA	Legal obligation
Distributor	Company B	Name and Address inside EEA	Optional
Authorised Representative		Name and Address inside EEA	Legal obligation

Figure 1

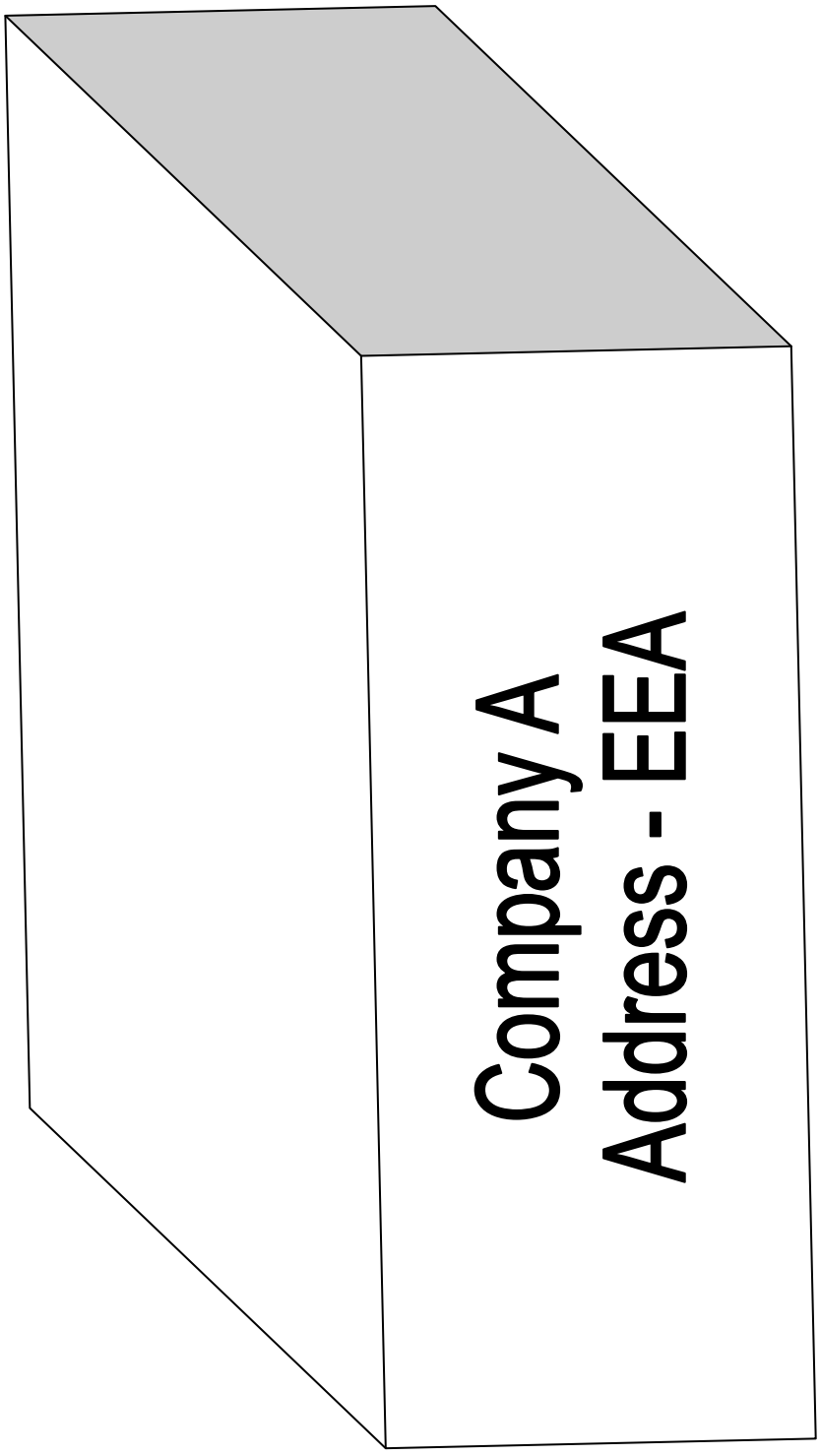

Figure 2

Optional
Distributed by:
Company B
Address - EEA
Company A Logo
Company A Logo
Manufacturer: Company A
Address - EEA
Legal obligation

3 Figure3

Optional
Distributed by:
Company B
Address - EEA
Company B Logo
Company B Logo
Manufacturer: Company A
Address - EEA
Legal obligation

Figure 4

Optional
Company A Logo
Distributed by: Company B
Address - EEA
Company A Logo
Manufacturer: Company A
Address - Outside EEA
Legal obligation
Aut. Rep or importer:
Name
Address - EEA
Legal obligation
to add legal responsible person as appropriate
under Medical Devices Directives

Optional

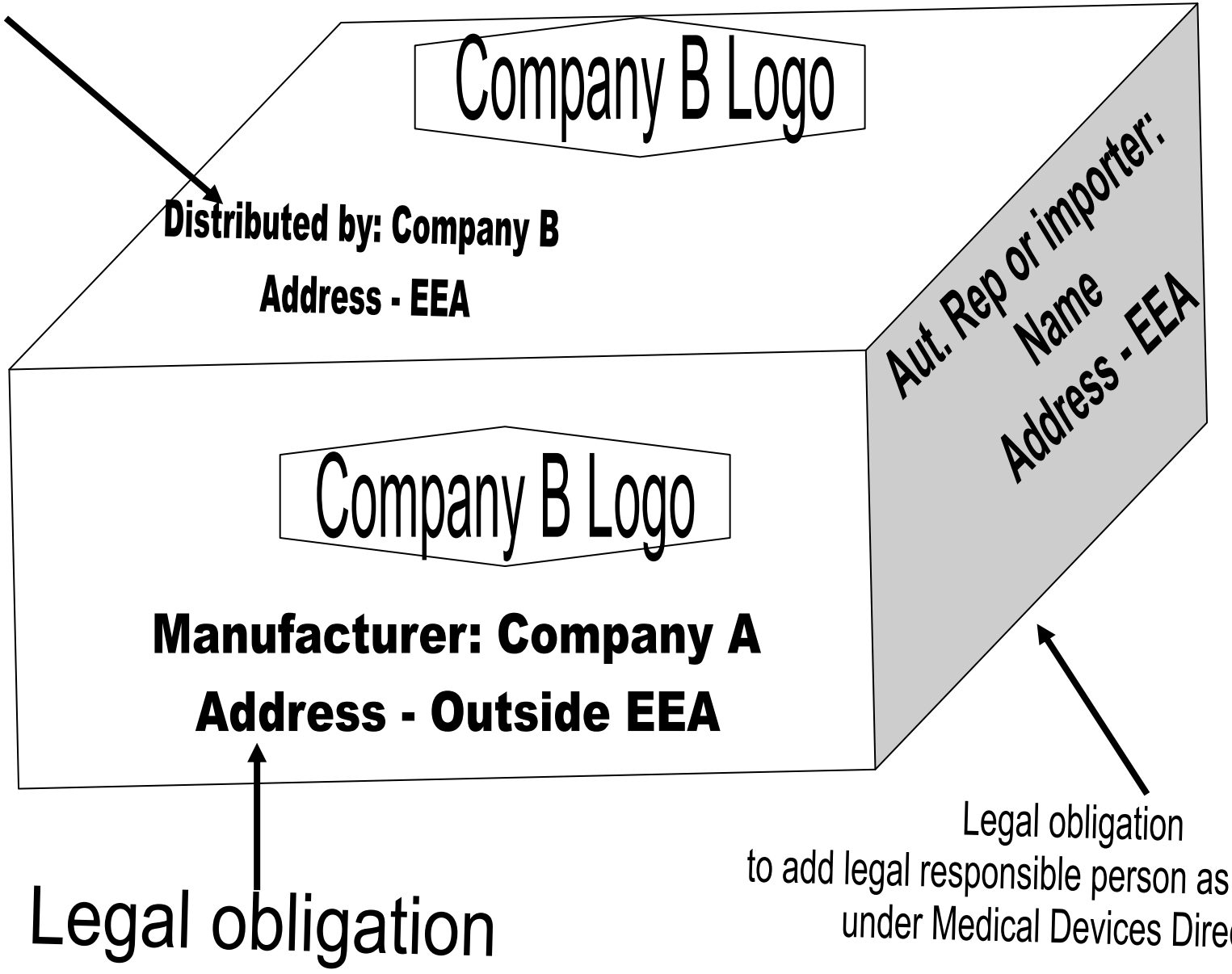

Figure 5