Information about custom-made products

Introduction
It might not always be possible to adapt a CE-marked product to suit the special needs of a user; in which case it could be possible to make a custom-made product for that particular user. Below we have set out information about the responsibilities, rules, requirements, etc. for these custom-made products.

Combined products or custom-made product?
Combining CE-marked units/components to achieve a functional solution for an individual patient is not deemed to be a custom-made product if all the parts and components are used in accordance with the manufacturers' instructions.
If personnel within assistive aid businesses combine CE-marked products that are not intended to be combined with each other, the manufacturer's product safety liability ceases to apply. At the same time, the manufacturer's responsibility is transferred to the party responsible for the new combination. It is always the manufacturer (i.e. the party responsible for the CE marking) that should assess and declare how its own products can be combined with other products.

It might happen that a company claims to take responsibility for a combination of two or more products without that combination being stipulated as approved by all the manufacturers of the parts/components included in the combination. The manufacturer that asserts the compatibility of the parts/components should be able to verify that the combination, including the interface, is safe, and that the promised combination provides the promised performance.

In theory, a custom-made product can arise through:

- available products being combined in a way that no manufacturer takes responsibility for.
- design-related changes (additions) being made to a finished product.
- the design and manufacture of a new product.
- the product being used in a new way or within a new area of use.

Definition of a custom-made device according to paragraph 2 of LVFS (The Swedish Medical Products Agency's provisions and guidelines) 2009:18:
"Any device that has been specifically made in accordance with a duly qualified medical practitioner's written prescription which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The above-named prescription may also be made out by any other person authorised by virtue of his professional qualifications to do so."

Responsibility
The medical practitioner is responsible for ensuring that the order is correct and that the device is "installed" in the correct manner at the place of use by the patient/user.
The responsibility for the design and manufacture in order to comply with the prescription rests with the manufacturer, in exactly the same way as for commercially available medical devices.

The above means that a dialogue between the prescriber and the manufacturer is necessary in most cases in order to ensure the manufacture of a solution that is good for the user. During the risk analysis, consideration must be given both to the risks that arise in conjunction with the technical solution, and the risks that can be attributed to the functional analysis. An overall assessment must be carried out.

Registration of manufacturers
Manufacturers of medical devices should be registered with the Swedish Medical Products Agency (LVFS 2003:11, paragraph 9). In this context, the term “manufacturer” refers to, among other things, the workshops or other units that design and/or manufacture custom-made products. This applies to assistive aid centres, vision assistance centres, hearing assistance centres and orthopaedic departments as well as independent workshops that manufacture custom-made products.

Essential requirements
Custom-made products may only be released onto the market and put into use if they fulfil the conditions set out in paragraph 7 in combination with annex 8. Products in Class IIa, IIb and III should be accompanied by the statement stipulated in annex 8 and should be available to the patient referred to in the prescription that has been issued. (The above-named paragraph and annex can be found in LVFS 2003:11)

In principle, a custom-made device should fulfil the same requirements as apply to all other medical devices (in other words it should be safe and should be suitable for the use for which it is intended). However, there is a possibility, based on medical reasons, to deviate from one or several essential requirements (LVFS 2003:11, annex 1). Any deviations should be documented and justified in the declaration that must be produced for every custom-made product. Risks should primarily be eliminated by way of design measures, and if the risk analysis indicates the existence of remaining risks, those risks should be functionally and medically defensible. The user should be informed about the device’s characteristics. This is particularly pertinent if the customisation has entailed increased or new risks during use of the device.

Choice of materials etc.
The work that must be carried out to show that a custom-made product complies with the essential requirements is affected by the choice of starting products. If the starting point for the customisation is a CE-marked product (according to LVFS 2003:11), in many cases it can be a relatively simple process to analyse and document the changes that the customisation has given rise to. If, on the other hand, the starting point for the customisation is a non CE-marked product, the documentation of the customisation must deal with all the essential requirements.

The same thing applies to the choice of materials for the manufacture of ear moulds for hearing aids, prosthetic sockets, orthoses, thoracic supports, etc. The requirements regarding the materials that are to be included are affected by the use of those materials. The requirements become more stringent in cases of, for example, prolonged contact with bare skin and direct contact with sores and infected skin.

It many cases it can be difficult to show that a special material is suitable for a certain type of use, and the methods that need to be resorted to can often be unreasonably complicated/expensive when they must be applied to an individual customisation. By choosing materials whose suitability has already been verified by the manufacturer, the work involved with the customisation will be made easier.

Marking
All medical devices should be marked so that they can be identified and so that the manufacturer can be traced. Since custom-made devices are manufactured as one-offs, the requirement regarding identification means that each individual custom-made product should be able to be identified and that the marking should enable this identification.

Furthermore, a custom-made device should be marked with the words “Custom-made device”. Otherwise, the requirements for the marking of custom-made devices are no different from the requirements that generally apply in accordance with the essential requirements set out in LVFS 2003:11, annex 1, item 13.

Example:
Custom-made Device No: 321
The Assistive Aid Centre in X-Town
123 45 X-Town

Furthermore, the CE marking should be covered over by the above-named label or, alternatively, removed, since a custom-made product should not be CE-marked.

For combined products that consist of several modules/products that are themselves CE-marked, it is possible to proceed in the following ways:

- If all the units are part of a system that can be combined with each other and the customisation consists of a change to one of these units, in most cases it is sufficient to simply remove, or conceal, the CE marking on the custom-made unit. In certain cases, however, the base unit can be affected to such a degree that the CE marking on the base unit must also be removed.

- If the customisation is achieved through the use of an "unauthorised" unit, for example a footrest from another manufacturer, the CE marking should be removed, or concealed, on this unit as well as on the unit to which it is connected. Furthermore, the CE marking on the product's base unit should also be removed or concealed.

- If the customisation is achieved through a combination of units that are not intended to be combined with each other, the CE marking should be removed, or concealed, on all these units. Furthermore, the CE marking on the product's base unit should also be removed or concealed.

- If the customisation is achieved through a product being used in a non-intended manner, all CE marking should be removed or concealed.

In certain individual cases it can be difficult, or even impossible, to remove or conceal the original CE marking. In these cases the custom-made device label is deemed to take over from the CE marking.

User information
The party that produces the user instructions for a custom-made medical device is also responsible for ensuring that the user receives the necessary knowledge about the product, its functionality and its characteristics. The user should be able to manage and use the device in a safe manner. The requirements relating to this information are no different from the requirements relating to other medical devices or the requirements relating to consumer products.

If a commercially available product is customised and the original product's user information/instructions are used, a complete set of user instructions should be provided in which:

- it is highlighted (not cut and pasted) which sections no longer apply and where references to any replacement sections have been included.

- supplemental information is provided that is necessary in relation to the customisation.
  It is often appropriate for such supplemental information to be provided in the form of appendices to the original user instructions.

Every part of the user information/instructions should be marked so that they can be identified and placed together with the correct custom-made device. It is important that it is made apparent how the customisation has affected the device, and who has produced the instructions.

Furthermore, the device may need to be equipped with additional marking, for example warning texts and/or instructions.

Monitoring and documentation of custom-made products

In LVFS 2003:11, annex 8, it is stated that manufacturers of custom-made devices should undertake to establish and maintain a system for monitoring and documenting information and experiences from the practical use of custom-made devices, and to establish suitable methods for the taking of necessary corrective measures. This undertaking also includes providing the necessary information to the relevant authorities.

The manufacturer of a custom-made product should also produce a statement that, among other things, should contain information about product identification, the manufacturer and its address, the identity of the prescriber, the product's special characteristics as they are set out in the instructions, confirmation that the product complies with the essential requirements and, in applicable cases, a description of which essential requirements that aren't fully complied with, along with the reasons why. This statement should be available to the user/patient in question and should accompany products in Class IIa or higher. The documentation should also make it possible to understand the design and the anticipated performance of the product, so that compliance with the requirements set out in the regulations can be assessed. The statement should be kept for at least five years, although it is recommended that it be saved for even longer (e.g. for 5 years after scrapping), since the product life is sometimes significantly longer. Manufacturers of custom-made products should also be able to present a list of the products that have been put into use in Sweden as and when such a list is requested by the Swedish Medical Products.

The information that exists in the instructions should be available to the care giver and should be stored in accordance with the care giver's written procedures. More comprehensive drawings, calculations and the like can be archived at the premises of the party that has carried out the technical work. It is always the party that has produced the instructions for the custom-made product that is responsible for ensuring that the collective information complies with the requirements set out in the regulations, regardless of where that information is kept or stored.

Reuse of a custom-made product

Only the original manufacturer can restore a custom-made product to a "CE-marked product". If the care giver, or any other party, restores a product without the manufacturer's approval, the care giver or the other party in question then takes over the responsibility for the product. This means that the product must be deemed to be a new product and must be made available for use as

- an entirely new product that has been CE-marked by the new manufacturer,
- a self-made product, or
- a new custom-made product.