Intended Use and Clinical Claims

As can be noted from previous section, **the intended use of the software is the key definition** whether the software is a medical device or not. Therefor the next step is to define this intended use:

> Use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

Clinical claims are claims that will have patient benefits:

> The positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health.

An example of above intended use and clinical claims for a TENS device (a technique used to relieve pain in an injured or diseased part of the body in which electrodes applied to the skin deliver intermittent stimulation to surface nerves, blocking the transmission of pain signals):

The TENS is intended to be used by adult consumers who experience mild to moderate chronic pain or acute post-surgical pain. The device is suitable for home use. It provides pain relief through transcutaneous electrical nerve stimulation (TENS). It can be uses for electrical muscle stimulation (EMS).

Changing intended use and claims require a new CE submission! So, a possible strategy is to first submit a CE file with technical claims only and clinical claim that are already proven by equivalent products already on the market. Next, submit a CE file with extended clinical claims. Technical claims can be validated by means of bench testing (see section Verification and Validation): no use of human subjects needed (no clinical investigation).