Market, environment and objectives of CEN/TC 257 – Symbols and information provided with medical devices and nomenclature for regulatory data exchange,
as approved by resolution BTC 300/1999

Scope
Standardization of labelling requirements and symbols used in labelling in the field of medical devices and in SC 1 standardization of the identification, coding, nomenclature and data sets for medical devices to facilitate regulatory data exchange.

Market, Environment and Objectives
This section establishes a sequential development of thoughts regarding the Market for which the CEN/TC aims to fulfill the needs. This sequence of thoughts starts from a description of the current market situation relevant to the product or product grouping under consideration by the CEN/TC, continues on to an analysis of the different factors motivating/influencing the activities of the CEN/TC, to come to a clear description of objectives for the CEN/TC, together with an accompanying strategy how to reach those objectives. Finally, a general ‘risk analysis’ is included highlighting issues that may delay or stop the CEN/TC achieving its set objectives.

Market Situation

The work programme is mandated by mandates M/BC/CEN/89/9 (Medical devices), M/023 (Medical devices) and M/252 (In vitro diagnostic medical devices).

The standards developed by TC 257 are horizontal standards which are intended to cover medical devices and materials in general. In principle, all products falling under these directives are covered by the work of the TC. The market for medical devices and companies operating in it are in many cases international. Since TC 257 covers all medical devices, from simple syringes to very complex implants and electromedical equipment, it is difficult to consider factors such as market share, structure of the market or product groups, or the turnover of the companies involved as criteria for justifying the existence of TC 257, and are consequently not detailed here. Suffice to say that the global medical device industry is very large, highly competitive and tends to be dominated by the US based companies. The work of TC 257 contributes to the further development of the European Single Market and to the health and safety of European patients.

SC1 was established specifically to manage the development of standards covering medical device nomenclature. This is driven by the growing market need of regulatory bodies within
national governments, and from medical device manufacturers throughout the world to exchange information on medical devices unambiguously, easily and quickly.

**Market Environment**

Political, economical, social, technical, legal and international factors that either directly require some or all of the standardization activities proposed by the CEN/TC, or significantly influence the way these activities are carried out are the following:

The standardization activities are mainly required to improve the efficiency of the new legal system created by the medical device directives.

The standards on symbols and labelling provide interpretation of the relevant essential requirements and thus have a clear benefit for the safety of patients. The use of harmonized symbols reduces the need for translation into national languages and therefore has a clear economic benefit for the manufacturers, and ultimately, the purchasers.

The standards relating to a nomenclature of medical devices are absolutely crucial in order to record, communicate and analyse regulatory information and data on medical devices (in particular regulatory compliance information and adverse incident reporting).

In order to compete in the worldwide market, it is important to have a large single home market. The standards developed by TC 257 contribute to the creation of uniform rules and the elimination of technical barriers to trade and thus support the construction of the Single Market of the European Economic Area (EEA). There are also direct links to ISO work, thus fostering the reduction of technical barriers to trade in the global market.

Interested parties include, in the first place, manufacturers of medical devices and their authorized representatives within EU, as well as regulatory authorities and hospitals and other health care facilities and practitioners who use the devices on patients. For certain products also the home-use of products by non-professionals must be kept in mind.

**Objectives of the CEN/TC and Strategies for their Achievement**

**Objectives of the CEN/TC**

Standardization within TC 257 is mostly based upon mandates from the EU Commission and the EFTA Secretariat.

The basic standards on symbols and labelling of medical devices have been issued. However, there is a clear need for new symbols in order to facilitate regulatory compliance. EN 980 is therefore undergoing revision. It is likely that further revisions will be needed from time to time as new problems arise.

Completion of the work to develop the medical device nomenclature system would also ensure that Competent Authorities, Notified Bodies, hospitals etc. communicate information related to medical devices using the same medical device names. Without this system, it will be very difficult to share or analyse information and data. The new system is of critical importance for regulatory enforcement across the EEA and for assessing risks (adverse incident reporting) with any medical device that is on the market.
Strategies adopted to reach the Objectives

European standards which have been mandated are prepared as a priority. Non-mandated, user-related standards are prepared only by specific demand, preferably in the framework of the Vienna Agreement.

Standards work regarding labelling and information provided with medical devices is allocated to a WG directly under the TC. For the standardization of nomenclature a separate subcommittee, SC 1, has been set up.

TC 257 has liaisons with COCIR, EUCOMED and EUROM IV. TC 257 also has cooperation by participation in the meetings with CEN/TC 140, 204, 205, 251, 285, CENELEC/TC 62 and ISO/TC 210.

Part of the work of SC 1 is in parallel with ISO/TC 210 under the Vienna Agreement (CEN Lead).

Risk analysis

Resources and continued motivation of all partied concerned are crucial factors for the completion of the proposed work programme. It is expected that the necessary resources and expertise will be available. Work is also greatly dependent on the EU legislation, which can be considered to define certain limits and requires intense cooperation with the European Commission. There has been in the past differences of opinion between the Commission on one hand and other interested parties on the other hand which has slowed down the adoption and harmonization process.

In SC 1 parallel work in hand in ISO/TC 210 may encounter difficulties if ISO/CEN work diverges. It is important that the final system developed gains worldwide acceptance.