BUSINESS PLAN

CEN/TC 102
STERILIZERS and ASSOCIATED EQUIPMENT FOR PROCESSING MEDICAL DEVICES

EXECUTIVE SUMMARY

Business environment

CEN/TC 102 is engaged in the standardization of washer-disinfectors, sterilizers and associated equipment and products used in the processing of medical devices.

CEN/TC 102 operates in close cooperation with ISO/TC 198 "Sterilization of health care products".

The following European Council New Approach Directives or Regulations are relevant to the work of CEN/TC 102:

- 93/42/EEC on medical devices
- Regulation (EU) 2017/745 on medical devices
- 90/385/EEC on active implantable medical devices
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices
- 2014/68/EU on pressure equipment.

Benefits

The standards developed by CEN/TC 102 support the uniform implementation of the requirements of the above-mentioned European Council Directives or Regulations, if applicable.

The standards developed by CEN/TC 102 support the needs of industry but also of notified bodies, competent authorities, healthcare facilities, patients and other users of sterilized medical devices.

Priorities

CEN/TC 102 seeks to develop and maintain relevant up to date standards on sterilizers, washer-disinfectors and associated accessories with the objective to ensure satisfatory cleaning, disinfection, sterilization and sterile products until the point of use.

1 BUSINESS ENVIRONMENT OF THE CEN/TC

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards.

During the preparation and maintenance of standards on sterilizers, washer-disinfectors and associated accessories, CEN/TC 102 considers the developments in sterilization technologies but also in the design and construction of the medical devices that need to be processed. These developments include new sterilization processes, new equipment and techniques used for the monitoring of sterilization processes, new and very often sophisticated design of medical devices including the new materials used for their construction. These developments are a great challenge for CEN/TC 102 during the development of appropriate requirements and test methods for the equipment and for its associated accessories.

Sterilizers, washer-disinfectors and their associated accessories are used in different fields of applications. These comprise very large companies, healthcare facilities of different size but also rather small general medical practices, dental practices and others. Standards of CEN/TC 102 have to address their specific needs and conditions.

The standards activities of CEN/TC 102 are also affected by the recent developments in the fields of pressure equipment and operator safety. The corresponding standards (EN ISO 14971, EN ISO 12100, series EN 13445, EN 61010-1 and EN 61010-2-040*)* have been taken into consideration or will be considered during the revision of existing standards of CEN/TC 102. The responsibility for EN 14222 has been handed over in 2016 to CEN/TC 102.

A large number of the projects and standards of CEN/TC 102 are mandated and are already (or will become in the near future) Harmonized European Standards. The relevant European Council Directives are the Directives 93/42/EEC on medical devices, 90/385/EEC on active implantable medical devices and 2014/68/EU on pressure equipment.
CEN/TC 102 wishes to align standardization of equipment standards for sterilizers with a potential EU Commission’s standardisation request for the medical devices regulation and/or in vitro diagnostic regualtion, respectively.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN/TC.

The main focus of CEN/TC 102 during the elaboration of its Standards is to ensure satisfactory cleaning, disinfection, sterilization and sterile products until the point of use.

Standards of CEN/TC 102 are used as normative references in the standards on development, validation and routine control of sterilization processes prepared / in preparation by CEN/TC 204 and ISO/TC 198 (in particular the standards on indicators, packaging materials and washer disinfectors).

A large number of different parties require the standards of CEN/TC 102. These include manufacturers of sterilizers, washer-disinfectors, packaging materials and -systems (single use and re-use), biological and chemical indicators, manufacturers of medical devices and notified bodies, competent authorities, healthcare facilities, patients and other users of sterilized medical devices. As for the industrial parties, both multinational and SME's are involved.

The export and import of the products covered by the scope of CEN/TC 102 is not confined to the European market.

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC

The standards developed by CEN/TC 102

- assist manufacturers of sterilizers, washer-disinfectors and their associated accessories to demonstrate fulfillment of the applicable Essential Requirements of the Medical Device Directive or the General Safety and Performance Requirements of the Medical Device Regulation and In vitro Diagnostic Regulation and provide manufactures, notified bodies, test houses with a clear route to CE marking;
- assist manufacturers of sterilizers and their associated accessories to demonstrate fulfillment of the applicable Essential Requirements of the Pressure Equipment Directive and provide manufactures, notified bodies, test houses with a clear route to CE marking;
- assist purchasers and users of sterilizers, washer-disinfectors and their associated accessories to select, to procure and to take into operation respective equipment certified to be compliant to the applicable European Directives and Regulations (EC), and compliant to the state of the art as specified by these standards;
- create pre-requisites for the re-use of medical devices;
- contribute to the elimination of trade barriers and favour the global market in particular by the application of the Vienna Agreement with ISO/TC 198;
- support SME's;
- reduce costs by rationalisation of specifications for sterilizers, washer-disinfectors and associated equipment particularly with regard to dimensions and performance, to allow interchangeability;
- result in improved equipment including accessories that will allow that sterile medical devices will provide sterility until the point of use;
- ensure that equipment and accessories are supplied with the appropriate instructions and technical performance;
- provide agreed test methods;
- consider environmental aspects.

3 PARTICIPATION IN THE CEN/TC

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC

The objectives of CEN/TC 102 are to develop and maintain up to date standards and other deliverables on sterilizers, washer-disinfectors, single use and re-usable packaging materials and systems, biological and chemical indicators in order

- to ensure satisfactory cleaning, disinfection and sterilization;
- to ensure that terminally sterilized medical devices maintain the sterile state until the point of use;
- to develop standardized performance test procedures and indicator and monitoring systems;
- to promote uniformity and clarity in understanding by adoption of standardized terminology.

The standards address the different sterilants applied but also the different fields of applications.

4.2 Identified strategies to achieve the CEN/TC's defined objectives.

- CEN/TC 102 has established standards on sterilizers, packaging materials and –systems, biological and chemical indicators, washer-disinfectors and stainless steel steam boilers. These standards have been prepared on the basis of former national standards. Most of these standards are currently under revision. This revision is being carried out in close co-operation with ISO/TC 198 "Sterilization of health care products" (where applicable).
- The application of the Vienna Agreement is also the preferred route for the development of new standards and other deliverables in order to avoid duplication of work. Both routes, ISO and CEN lead, are applied.
- Liaisons have been established with other TCs in order to ensure coherency of standards work. These other Technical Committees are:

  CEN/TC 54 "Unfired pressure vessels", CEN/TC 55 "Dentistry", CEN/TC 204 "Sterilization of medical devices", CEN/TC 205 "Non-active medical devices", CEN/TC 216 "Disinfectants", CEN/TC 233 "Biotechnology", CEN/TC 261 "Packaging", CEN/TC 269 "Shell and water tube boilers", IEC/TC 66/CLC/SR 66 "Safety of measuring, control, and laboratory equipment" and ISO/TC 198 "Sterilization of health care products".
- CEN/TC 102 welcomes the input of relevant European organizations and has established liaisons with:

  MedTech Europe European trade association representing the medical technology industries from diagnosis to cure, a alliance of EDMA (European Diagnostic Manufacturers) and Eucomed (European Medical Technology Industry Association) and SBA (Sterile Barrier Association).
- The main focus is given on the development of European Standards but other types of deliverables (Technical Specification and Technical Report) are also developed or in preparation.
- The work is carried out in working groups. If required, Joint Working Groups and ad hoc groups will be arranged at TC level and Working Group level respectively. In case of the application of the Vienna Agreement the TC and its WGs monitor the work of ISO/TC 198 to ensure that the resulting standards will meet the needs of the Medical Device Directive or Medical Device Reguation and In-vitro-Diagnostic Device Regulation.

4.3 Environmental aspects

The documents elaborated by CEN/TC 102 consider the potential impacts on environment of a product that can occur during all stages of its life cycle, e.g. environmental aspects along the design, operation and dismantling. These impacts range from slight to significant; however, safety aspects (Medical Device Directive, Medical Device Regulation, In-vitro-Diagnostic Device Regulation) will always have priority over environmental aspects.

CEN/TC 102 intends to consider environmental issues for all New Work Item proposals and will be compliant with CEN Guide 4 to determine if it is possible to deal with an environmental issue through a product standard. The relevant environmental aspects already have to be reflected when asking for a New Work Item and it is recommended to include an environmental checklist according to CEN Guide 4 as informative annex to these standards. Furtheremore, the TC will conduct reviews of product standards whenever any environmental impact might be significantly reduced by application of new knowledge and technology.

Up to now several standards have been developed (e.g. EN 1422,EN 14180 and EN ISO 11607-1) using the checklist according to CEN Guide 4 as informative annex, i.e. assessment of dangerous substances like ethylene oxid.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC WORK PROGRAMME

Resources and continued motivation of all parties concerned are crucial factors for the successful work of CEN/TC 102. The necessary expertise is anticipated and has been found thus far. However, difficulties may arise during the development of new test methods as the carrying out of the required test programme depends upon funding through interested companies.