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Standards reflect the state of the art, but have no legal character. However, state authorities and similar institutions will have to proceed on the assumption that products which conform to harmonized standards and have the CE-mark will also conform to all EEC guidelines, i.e. to all applicable laws. The EEC Council has appointed the Comité Européen de Normalisation (CEN) (European Committee for Standardization) and CENELEC (for electro-technical standards) to issue those European standards.

The nomenclature for standards is somewhat confusing. European standards start with the letters EN. Drafts for these standards start with the letters prEN, with "pr" being derived from "preliminary". European standards are issued in three official language versions, English, French and German. In addition, each country may translate European standards into the respective official language(s), for this translation the country will then be held responsible.

In this case the symbol of the country is put in front of EN like in Germany DIN EN 285.

International standards are issued by the International Organization for Standardization ISO. Their identification starts with the letters ISO. The official language versions are English, French and Russian. International electro-technical standards have a designation beginning with the letters IEC. The first draft of an ISO standard is marked by the letters CD (= Committee Draft); the final draft is marked by DIS (Draft International Standard), e.g. ISO/DIS 13683.

European standards must be adopted by all member countries of CEN/CENELEC; national standards or parts thereof covering the same content become obsolete. For instance, DIN EN 285 has replaced DIN 58946 Part 2.

European standards concerning sterilization are developed by the working groups CEN/TC 102 and 204. Until 2001 these working groups have created standards for sterilizers, for biological and chemical indicators and for the validation of sterilization processes. A big part of these standards has been consolidated with the International ISO standards. Details are presented on the following three attachments.