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Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process

(ISO 10993-18:2020, IDT)

医疗器械生物学评价 第 18 部分：风险管理过程中医疗器械材料的化学表征

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Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Medical Device Materials within a Risk Management Process

1 Scope

This Document specifies a framework for the identification, and if necessary, quantification of constituents of a medical device, allowing the identification of biological hazards and the estimation and control of biological risks from material constituents, using a generally stepwise approach to the chemical characterization.

This Document applies to one or more of the following:

— the identification of its materials of construction (medical device configuration);

— the characterization of the materials of construction via the identification and quantification of their chemical constituents (material composition);

— the characterization of the medical device for chemical substances that were introduced during manufacturing (e.g., mold release agents, process contaminants, sterilization residues);

— the estimation (using laboratory extraction conditions) of the potential of the medical device, or its materials of construction, to release chemical substances under clinical use conditions (extractables);

— the measurement of chemical substances released from a medical device under its clinical conditions of use (leachable).

This Document can also be used for chemical characterization (e.g., the identification and/or quantification) of degradation products. Information on other aspects of degradation assessment is covered in ISO 10993-9, ISO 10993-13, ISO 10993-14 and ISO 10993-15.

The GB/T (Z) 16886 (all parts) is applicable when the material or medical device has direct or indirect body contact (see ISO 10993-1 for categorization by nature of body contact).

This Document is intended for suppliers of materials and manufacturers of medical devices, to support a biological evaluation.

Chemical characterization of a medical device provides the necessary input into the device's biological evaluation and toxicological risk assessment (see ISO 10993-1 and ISO 10993-17). A flowchart describing the general chemical characterization process is given in Figure 1. This flowchart represents the chemical characterization portion of the overall biological evaluation flow as discussed in ISO 10993-1 and is meant to illustrate the characterization process that is described in this clause. This general flowchart is supplemented with additional flowcharts (see Figures 2 to 4) that provide greater detail to specific steps in the general process.

The requirements and guidance for each step of the chemical characterization process are specified in 5.2 to 5.10. When specified in the applicable flowchart, knowledgeable and experienced individuals shall compile existing information relevant to the chemical characterization (information gathering) and assess its adequacy as the basis for a toxicological risk assessment of the material/medical device. If the existing information is insufficient to complete the assessment, additional information shall be gathered or produced by testing (information generation) to enable the toxicological risk assessment.

This procedure should consider each of the direct and indirect contact materials of construction used in a medical device in addition to the requirement for chemical characterization of the finished medical device. Since the chemical nature of a medical device can be affected by its processing during its construction (e.g., sterilization), the effect of this processing on the device shall be taken into account in the design and interpretation of the chemical characterization.

At each step of the characterization procedure, the adequacy of the available data as the basis for performing the risk assessment shall be established. The available data can be considered adequate if it reflects or exceeds the conditions of clinical use and a risk assessment based on the available data can be completed. Inadequacies in the data can be addressed by filling gaps in such data (e.g., literature review) and/or supplementing the data via analytical testing.

The flowcharts have the following types of process steps; start/stop, decision points, information gathering and evaluation, and analytical testing. Each type of step is represented by a geometric shape. Start/stop steps are identified as ovals, a decision step is identified as a diamond, an information gathering/evaluation step is represented as a parallelogram, and a step that involves analytical testing is represented as a rectangle.

The steps and actions defined in 5.4.2, 5.7 and 5.9 are part of the risk assessment process and represent the points at which chemical information is provided for assessment. As such, they are for the most part, outside the scope of chemical characterization, which is the focus of this document. These steps are included to indicate the important link between chemical characterization and risk assessment (see ISO 10993-1, ISO 10993-17, and ISO 14971).

The characterization procedure and its associated flowchart system is based on the principles in ISO 10993-1; specifically, that the biological evaluation and toxicological risk assessment process is most efficient and effective if it is based on the appropriate (minimum) amount of acceptable and necessary chemical information that can establish that a medical device presents an acceptable health risk. Thus, the first step of the procedure is to establish the configuration

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