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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 16886.17-2005

**Biological evaluation of medical devices -- Part 17:
Establishment of allowable limits for leachable substances
(English Translation)**

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1 Scope

This Part of GB/T 16886 specifies a method for the determination of allowable limits for substances leachable from medical devices. It is intended for use in deriving standards and estimating appropriate limits where standards do not exist. It describes a systematic process through which identified risks arising from toxicologically hazardous substances present in medical devices can be quantified.

This Part is not applicable to devices that have no patient contact (e.g. in vitro diagnostic devices).

Exposure to a particular chemical substance may arise from sources other than the device, such as food, water or air. This Part does not address the potential for exposure from such sources.

2 Normative references

The following standards contain the provisions which, through reference in this

Part of GB/T 16886, constitute the provisions of this Part. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Part. However, the parties who enter into agreement based on this Part are encouraged to investigate whether

the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this

Part.

GB/T 16886.1, Biological evaluation of medical devices - Part 1. Evaluation and testing (GB/T 16886.1-2001, idt ISO 10993-7.1997)

3 Terms and definitions

For the purposes of this Part of GB/T 16886, the terms and definitions given in

GB/T 16886.1 and the following apply.