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

GB/T 16886.2-2011

**Biological evaluation of medical devices -- Part 2: Animal
welfare requirements**

医疗器械生物学评价 第2部分：动物福利要求
(English Translation)

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1 Scope

This part of GB/T 16886 is aimed at those who commission, design and perform tests or evaluate data from animal tests undertaken to assess the biocompatibility of materials intended for use in medical devices, or that of the medical devices themselves. It specifies the minimum requirements to be satisfied to ensure and demonstrate that proper provision has been made for the welfare of animals used in animal tests to assess the biocompatibility of materials used in medical devices, and form the relevant documents.

It also makes recommendations and offers guidance intended to facilitate future further reductions in the overall number of animals used, refinement of test methods to reduce or eliminate pain or distress in animals, and the replacement of animal tests by other scientifically valid means not requiring animal tests.

It applies to tests performed on living vertebrate animals, other than man, to establish the biocompatibility of materials or medical devices.

It does not apply to tests performed on invertebrate animals and other lower forms; nor (other than with respect to provisions relating to species, source, health status, and care and accommodation) does it apply to testing performed on isolated tissues and organs taken from vertebrate animals that have been euthanized.

2 Normative References

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and
Testing within a Risk Management Process

3 Terms and Definitions

For the purposes of this document, the definitions given in ISO 10993-1 and the