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前 言

GB/T 16886《医疗器械生物学评价》由下列部分组成：

- 第 1 部分：风险管理过程中的评价与试验；
- 第 2 部分：动物福利要求；
- 第 3 部分：遗传毒性、致癌性和生殖毒性试验；
- 第 4 部分：与血液相互作用试验选择；
- 第 5 部分：体外细胞毒性试验；
- 第 6 部分：植入后局部反应试验；
- 第 7 部分：环氧乙烷灭菌残留量；
- 第 9 部分：潜在降解产物定性与定量构架；
- 第 10 部分：刺激与迟发型超敏反应试验；
- 第 11 部分：全身毒性试验；
- 第 12 部分：样品制备与参照样品；
- 第 13 部分：聚合物降解产物定性与定量；
- 第 14 部分：陶瓷降解产物定性与定量；
- 第 15 部分：金属与合金降解产物定性与定量；
- 第 16 部分：降解产物与可沥滤物毒代动力学研究设计；
- 第 17 部分：可沥滤物允许限量的建立；
- 第 18 部分：材料化学表征；
- 第 19 部分：材料物理化学、形态学和表面特性表征；
- 第 20 部分：医疗器械免疫毒理学试验原则和方法。

本部分为 GB/T 16886 的第 16 部分。

本部分按照 GB/T 1.1—2009 给出的规则起草。

本部分代替 GB/T 16886.16—2003《医疗器械生物学评价 第 16 部分：降解产物与可沥滤物毒代动力学研究设计》，与 GB/T 16886.16—2003 相比，主要技术变化如下：

- 修改了“3 术语和定义”；
- 修改了“5 试验方法指南”；
- 修改了“附录 A 毒代动力学研究中应考虑的情况”，引入 ISO 10993-17、ISO 10993-18 和 ISO 14971 的内容。

本部分使用翻译法等同采用 ISO 10993-16:2010《医疗器械生物学评价 第 16 部分：降解产物和可沥滤物的毒代动力学研究设计》。

与本部分中规范性引用的国际文件有一致性对应关系的我国文件如下：

- GB/T 16886.1—2011 医疗器械生物学评价 第 1 部分：风险管理过程中的评价与试验 (ISO 10993-1:2009,IDT)；
- GB/T 16886.2—2011 医疗器械生物学评价 第 2 部分：动物福利要求 (ISO 10993-2:2006,IDT)；
- GB/T 16886.12—2005 医疗器械生物学评价 第 12 部分：样品制备与参照样品 (ISO 10993-12:2002,IDT)；
- GB/T 16886.17—2005 医疗器械生物学评价 第 17 部分：可沥滤物允许限量的建立