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医疗器械生物学评价　第10部分：刺激与迟发型超敏反应试验

Biological evaluation of medical devices—Part 10:Tests for irritation and delayed-type hypersensitivity

（ISO 10993-10:2002,IDT）

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前　言

GB/T 16886 的本部分等同采用国际标准 ISO 10993-10:2002《医疗器械生物学评价——第 10 部分:刺激与迟发型超敏反应试验》。

本部分经技术修订取代 GB/T 16886.10—2000,主要修订内容如下:

——修改了“总则与评价程序”;

——增加了“试验前的考虑”;

——增加了“人体皮肤刺激试验”;

——修改了“迟发型超敏反应试验”;

——将“皮内反应试验”和“眼刺激试验”由原标准正文中改为放在附录 B 中,作为特定部位应用医疗器械的适用刺激试验;

——将原标准中附录 A 和附录 B 的内容进行了综合修改,标题为“刺激和致敏试验用材料的制备”;

——修改了“背景信息”;

——取消了原标准附录 C。

GB/T 16886 的总题目是《医疗器械生物学评价》,由下列部分组成:

——第 1 部分:评价与试验;

——第 2 部分:动物保护要求;

——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 8 部分:生物学试验参照材料的选择与定量指南;

——第 9 部分:潜在降解产物的定性与定量框架;

——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:聚合物医疗器械的降解产物的定性与定量;

——第 14 部分:陶瓷降解产物的定性与定量;

——第 15 部分:金属与合金降解产物的定性与定量;

——第 16 部分:降解产物和可溶出物的毒代动力学研究设计;

——第 17 部分:可溶出物允许限量的确立;

——第 18 部分:材料化学表征。

有关其他方面的生物学试验将有其他部分的标准。

本部分是诸多标准和准则的协调产物,其中包括 BS 5736、OECD 准则、美国药典和欧洲药典。本部分为试验选择和实施的基本指南文献,以对医疗器械和材料安全性有关的刺激和皮肤致敏反应做出评价。

附录 A 为规范性附录,附录 B 和附录 C 为资料性附录。