

推荐性行业标准计划项目建议书

|                   |                                                                                                                                                                 |                 |                              |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|------------------------------|
| 项目名称<br>(中文)      | 牙科学 种植体与基台的旋转适应性测试                                                                                                                                              |                 |                              |
| 项目名称<br>(英文)      | Dentistry Rotational adaptability test between implant body and implant abutment in dental implant systems                                                      |                 |                              |
| 起草单位              | 北京大学口腔医学院口腔医疗器械检验中心                                                                                                                                             | 技委会或归口单位国内代号及名称 | SAC/TC99 全国口腔材料和器械设备标准化技术委员会 |
| 制定或修订             | 制定                                                                                                                                                              | 被修订标准编号         | /                            |
| 拟采用国际标准名称(中文)     | 牙科学 种植体与基台的旋转适应性测试                                                                                                                                              |                 |                              |
| 拟采用国际标准名称(英文)     | Dentistry Rotational adaptability test between implant body and implant abutment in dental implant systems                                                      |                 |                              |
| 国际标准号             | ISO 22683:2022                                                                                                                                                  | ICS分类号          | 11.060.10                    |
| 标准类别(注1)          | 方法标准                                                                                                                                                            | 一致性程度标识         | IDT                          |
| 计划起始时间            | 2025年1月                                                                                                                                                         | 计划完成时间          | 2025年12月                     |
| 目的、意义             | 种植体与基台之间的旋转适应性是一个重要的物理性能，该性能影响着种植体与基台之间的配合质量，从而影响抗松动的能力。此外，种植体与基台之间的正确适应性可以影响最终义齿的旋转定位、咬合精度和负荷下的物理行为。在评估牙科种植体系统的物理性能时需要测试旋转适应性，但目前尚无可用的国际标准，从而导致适应性测试方法和要求的差异性。 |                 |                              |
| 范围和主要技术内容         | 本文件规定了用于评估牙科种植体系统中种植体与基台之间的旋转适应性的试验方法。<br>本文件适用于种植体与基台之间不采用摩擦配合而是仅使用防旋转特性的种植体系统。在评估牙科种植体的适应性时，不得使用模拟件或复制件。<br>技术内容：测试方法。                                        |                 |                              |
| 主要强制的内容和强制的理由     | 不涉及                                                                                                                                                             |                 |                              |
| 与有关法律、法规和强制性标准的关系 | 与现行医疗器械法规、标准及已立项的计划项目没有交叉、重复或冲突。                                                                                                                                |                 |                              |
| 标准所涉及的产品清单        | 经查注册证，现行有效种植体注册证有100余例，例如：进口的瑞士士卓曼、韩国奥齿泰等，国产的创英、威高、百康特等。                                                                                                        |                 |                              |
| 国内外有关情况及发展趋势      | 为ISO现行有效的标准，无新版的制修订计划。                                                                                                                                          |                 |                              |

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| 制定标准拟采用的方法和技术依据 | 等同采用ISO 22683:2022。                            |
| 拟开展的主要工作（注2）    | 收集资料和相关产品，进行试验验证，试验方法确认，评判方法可行性，完成行业标准的起草制定工作。 |
| 与标准制修订相关的工作基础条件 | 1) 有技术大纲<br>2) 已有相关工作基础<br>3) 基本具备试验仪器和设备      |
| 合作单位与任务分工       | 待定                                             |

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| 项目预算 | 序号      | 列支项目                                     | 参考标准  | 数量 | 预算金额  |         |
|      | 1       | 出版印刷费                                    | 1     | 1  | 1     |         |
|      | 2.1     | 资料费                                      |       |    |       |         |
|      | 2.1.1   | 标准资料和相关资料的查询、检索费                         | 0.1   | 1  | 0.100 |         |
|      | 2.1.2   | 资料购买费                                    | 0.2   | 1  | 0.200 |         |
|      | 2.1.5   | 市场调研费                                    | 0.2   | 1  | 0.200 |         |
|      | 2.2     | 起草费                                      |       |    |       |         |
|      | 2.2.1   | 标准初稿、征求意见稿、送审稿、报批稿及相关附件（编制说明等文本）的编写、文字打印 | 0.9   | 1  | 0.900 |         |
|      | 2.2.2   | 校对费                                      | 0.7   | 1  | 0.700 |         |
|      | 2.2.3   | 印刷                                       | 0.2   | 1  | 0.200 |         |
|      | 2.3     | 试验费                                      | 1     | 1  | 1.000 |         |
|      | 2.4     | 差旅费                                      |       |    |       |         |
|      | 2.4.1   | 标准调研工作差旅费                                | 0.2   | 5  | 1.000 |         |
|      | 2.4.2   | 标准审定会专家差旅费（交通）                           | 0.1   | 5  | 0.500 |         |
|      | 2.4.3   | 工作组专家差旅费（交通）                             | 0.1   | 4  | 0.400 |         |
|      | 2.5     | 咨询费                                      | 0.05  | 10 | 0.500 |         |
|      | 2.6     | 验证费                                      |       |    |       |         |
|      | 2.6.1   | 标准验证装置研制、标准验证试验用品用具费用                    | 1     | 1  | 1.000 |         |
|      | 2.6.2   | 验证人员劳务费                                  | 0.35  | 4  | 1.400 |         |
|      | 2.7     | 会议费                                      |       |    |       |         |
|      | 2.7.1   | 标准审定会会议费                                 | 0.055 | 10 | 0.550 |         |
|      | 2.7.2   | 标准工作组研讨会                                 | 0.055 | 10 | 0.550 |         |
|      | 2.8     | 审查费                                      | 0.08  | 10 | 0.800 |         |
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| 起草审查                               | 起草 2025年1月至5月<br>审查 2025年9月至11月                                                                                                                             | 征求意见<br>报 批 | 征求意见 2025年6月至8月<br>批 2025年12月                                                                                |                |                  |
| 备注                                 | 2023 年 12 月，在北京市召开的 SAC/TC99 技委会工作会议上，对本立项项目进行技委会委员表决，内容包括标准名称、适用范围、标准性质、第一起草单位，全体委员一致同意。<br>关于在体系中位置的说明：本标准在标准体系中位置明确，位于口腔材料领域-材料门类通用标准-理化试验方法标准，是作用明显的项目。 |             |                                                                                                              |                |                  |
| 与相关的国际标准、国外区域或国家标准（如欧美日等）技术水平的对比情况 | 关于在体系中位置的说明：本标准在标准体系中位置明确，位于口腔材料领域-材料门类产品标准-牙种植体，是作用明显的项目。                                                                                                  |             |                                                                                                              |                |                  |
| 起草单位<br>意见                         | <br>(签字、盖章)<br>2024年9月27日                                                 | 技委会<br>意见   | <br>(签字、盖章)<br>2024年9月27日 | 主管<br>部门<br>意见 | (签字、盖章)<br>年 月 日 |

注 1：“标准类别”分为产品、基础、方法、管理、安全、其他。

注 2：“拟开展的主要工作”应包括调查、收集文献资料、试验、测试、方法标准验证、样品标准研制与定值、标准及编制说明的编写等项工作。

注 3：无标准草案或技术大纲的计划项目原则上不予批准。