

# Arcabouço legal da incorporação e acesso a dispositivos médicos no Brasil: estrutura, tipos de avaliação e oportunidades para avanços.

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## Abstract:

**Objective:** Present in a structured way the Brazilian legal framework related to the classification, nomenclatures and stages of adoption of medical devices into SUS and into Supplementary Health. **Methods:** Review and critical analysis of official publications and legal frameworks applicable to the regulation, adoption and access of medical devices in Brazil. **Results:** Based on the findings, it was possible to define the classifications and nomenclatures used by government agencies and mapping the flow of technological adoption, comprising four stages: a first national macroprocess of market incorporation from obtaining the health register at Anvisa, when the device becomes available for sale in the country; two other national macroprocesses for the definition of reimbursement and financing policies for the SUS and for the Supplementary Health that occur from submissions to Conitec and ANS; and, one process of local adoption with the acquisition by health facilities and services, representing the effective access to the population. **Conclusion:** The wide heterogeneity of medical devices makes the promotion of access to these technologies more challenging, requiring by Health Technology Assessment specialists a broader understanding of flows, classifications, strategies of assessment and possibilities for financing and reimbursement that have significant differences from those applicable to medicines. This work allowed to identify the main stages of adoption, suggesting the correction of detected weaknesses, as well as advances in order to promote medical devices access to the population with greater speed and efficiency.

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