Methodological Guidelines
For Medical Equipment Assessment Studies

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SUMMARY

1-INTRODUCTION
2-BACKGROUND
3-OBJECTIVE
4-METHOD
5-CONSIDERATIONS
INTRODUCTION

MEDICAL DEVICES

The term “medical devices” includes everything from highly sophisticated computerized medical equipment to simple wooden tongue depressors. (WHO)
BACKGROUND

FORMATION OF A WORKING GROUP (WG) IN THE EQUIPMENT AREA INTO THE BRAZILIAN GOVERNMENT

AGREEMENT TERM WITH THE INSTITUTE of BIOMEDICAL ENGINEERING/FEDERAL UNIVERSITY of SANTA CATARINA, BRAZIL

CONTRACTING A SPECIALIST REVIEWER (SAIDE CALIL, PhD)

12 INTERNAL MEETINGS OF THE EQUIPMENT WORKING GROUP

02 MEETINGS WITH THE EXECUTING TEAM;

EQUIPMENT WG PROPOSES A BASIC STRUCTURE FOR AN OUTLINE OF THE PROJECT

CONDUCT A RAPID REVIEW WORKSHOP WITH THE EXECUTING TEAM

CONDUCT A WORKSHOP FOR THE VALIDATION AND PRESENTATION OF CASE STUDIES

CONSENSUS MEETING AND FINAL REVIEW OF THE GUIDE
OBJECTIVE

General Objective: To develop an instrument that adds to the other already consacrated HTA methods, when the study’s theme deals with medical care equipment or procedures that include this technologies.

Specific Objectives: Methodology for HTA studies for medical care equipment.
METHODS

ARE THERE DIFFERENCES BETWEEN HEALTHCARE TECHNOLOGY ASSESSMENT FOR DEVICES AND FOR DRUGS?
DOMAINS

CLINICAL

ADMISSIBILITY

TECHNICAL

OPERATIONAL

ECONOMIC

INNOVATION
CONSIDERATIONS

DIGITAL MEDIA: CONTENT IN ENGLISH AND IN SPANISH, AND A CASE STUDY WITH THE DA VINCI ROBOTIC SYSTEM.

TO PROMOTE WORKSHOPS FOR APPLY THE TOOL IN REAL CASES ON BRASIL AND OTHER COUNTRIES.

TO ELABORATE THE SECOND VERSION

TO CREATE PARTNERSHIPS WITH OTHER GOVERNMENTS AND HTA AGENCIES
THANK YOU FOR YOUR ATTENTION.

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