Arab Republic of Egypt Egyptian Drug Authority Central Administration for Medical devices General Administration of Medical devices Registration





جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للمستلزمات الطبية الإدارة العامة لتسجيل المستلزمات الطبية إدارة تسجيل المستلزمات الطبية المحلية

Administration of Local medical devices Registration

Appraisal plan example

Criteria	Description	Grading System
Appropriate device	Were the data generated from the Device in question?	D1 Actual device D2 Equivalent device D3 Other device
Appropriate device Application	Was the device used for the same intended purpose (e.g., methods of Deployment, application, etc.)?	A1 Same use A2 Minor deviation A3 Major deviation
Appropriate patient	Where the data generated from a	P1 Applicable
Group	patient group that is representative of the intended treatment population e.g., age, sex, etc.) And clinical Condition (i.e., disease, including state and severity)?	P2 Limited P3 Different population
Acceptable report/data Collation	Do the reports or collations of data contain sufficient information to be able to undertake a rational and Objective assessment?	R1 High quality R2 Minor deficiencies R3 Insufficient information
Data source type	Was the design of the study appropriate?	T1 Yes T2 No
Outcome measures	Do the outcome measures reported reflect the intended Performance of the device?	O1 Yes O2 No
Follow up	Is the duration of follow-up long enough to assess whether Duration of treatment effects and Identify complications?	F1 Yes F2 No

Percentage of articles	Weight (High-Medium –Low)	Importance (A-B-C)
100-90%	High Contribution	Α
Less than 90% to75%	Medium Contribution	В
Less than 75%	Low Contribution	С

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