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

Ref No	Rev No.	Issue Date

Incident Report

1. Administrative information		
Recipient		
Name of national competent authority		
(NCA)		
Address of national competent		
authority		
Date of this report		
·		
Reference number assigned by the manufacturer		
Reference number assigned by NCA		
Type of report		
□ Initial report		
□ Follow-up report		
☐ Combined initial and final report		
□ Final report		
Does the incident represent a serious public health threat?		
□ Yes		
□ No		
Classification of incident		
□ Death		
☐ Unanticipated serious deterioration in state of health		
☐ All other reportable incidents		
Identify to what other NCAs this report was also sent		
2. Information on submitter of the report		
Status of submitter		
□ Manufacturer		
□ Others (identify the role):		
This is an example of some points only , so the manufacturer can increase or change this points		
regarding manufacturing process		

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