

Procedures for Issuing Replacements for Lost or Damaged Documents Year 2024

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Central Administration of Medical Devices



Procedures for Issuing Replacements for Lost or Damaged Medical devices registration license and its equivalents (IVD listing license/ Scientific committee approval)

- 1- **The company shall file a loss report at a police station, mentioning in it the medical device name – as stated in the registration license – the registration license number, and its expiry date.**
- 2- **The company shall submit a request to the secretary of the Central Administration for Medical Devices (CAMD) to issue a replacement for the lost registration license, to be attached with the following:**
 - Original copy of loss report issued by the police station
 - Delegation letter from the company with bank authentication of the signature
 - A commitment to submit the original copy in case it's found (commitment 1)
 - A copy of the lost license
 - The company shall submit a commitment (commitment 2) signed by the Chairman of the Board and bank-authenticated, stating that the company maintains an ongoing contractual relationship with the legal manufacturer of the medical device for which the registration license was issued, and that it has not handed over the original license to any other party.
 - An e-mail from the legal manufacturer of the registered medical device stating that their contract with the Egyptian agent / distributor that submitted a request to issue a replacement for the lost registration license is still valid
- 3- **A receipt of 500 EGP shall be paid by the company**
- 4- **After fulfilling the above requirements and verifying of the license data from the database of the relevant department, a copy of the registration license is issued stating on it the following statement:**

"بدل فاقد بناء على محضر الفقد ويثبت رقمه وتاريخه مع كتابة عبارة أنه لا يعمل بأصل الاخطار المفقود، وفي حالة ظهوره يتم تسليمه إلى جهة الإدارة"

Central Administration of Medical Devices



Procedures for Issuing Replacements for Lost or Damaged Import Approval

- 1- The company shall file a loss report at a police station, mentioning in it the final acceptance number of the import approval
- 2- The company shall submit a request to the secretary of the Central Administration for Medical Devices (CAMD) to issue a replacement for the lost import approval, to be attached with the following:
 - Original copy of loss report issued by the police station
 - A commitment from the company stating that the original copy of the import approval has not been used neither has they released what's included in the invoice of the lost import approval
 - A commitment from the company that in case of finding the original copy of the import approval, it has to be submitted to the central administration of medical devices and that the company will bear the legal responsibility in case of not submitting it or using it more than once.
 - A copy of the import approval
- 3- A receipt of 500 EGP shall be paid by the company
- 4- After fulfilling the above requirements and verifying of the approval data from the database of the relevant department, a photocopy of the import approval is issued stating on it the following statement:

" تم تحرير هذه الموافقة بناء على مذكرة الفقد رقم لسنة قسم شرطة وبناء على طلب الشركة "

Central Administration of Medical Devices



Commitment (1)

نتعهد نحن شركة بأنه في حالة العثور على أصل الإخطار المفقود الخاص بالمستلزم الطبي الذي يحمل رقم تسجيل سيتم تسليمه لإدارة متغيرات المستلزمات الطبية التابعة للإدارة المركزية للمستلزمات الطبية بهيئة الدواء المصرية، والذي تم تحرير محضر فقد له بقسم شرطة برقم في تاريخ

رئيس مجلس الإدارة

Commitment (2)

نتعهد نحن شركة بأننا مازلنا في علاقة تعاقدية سارية مع المصنع القانوني المسئول عن المستلزم الطبي والذي يحمل رقم تسجيل ، وأننا لم نسلم أصل إخطار التسجيل لأي طرف آخر أيا كان صفته.

رئيس مجلس الإدارة