

宜蘭縣政府衛生局 函

地址：260026宜蘭縣宜蘭市女中路2段287號

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260

宜蘭市女中路三段102號6樓

受文者：宜蘭縣藥師公會

發文日期：中華民國112年11月2日

發文字號：衛食藥字第1120030720號

速別：普通件

密等及解密條件或保密期限：

附件：美國FDA回收警訊及受影響產品批號

主旨：有關美敦力醫療產品股份有限公司總公司（下稱美敦力總公司）發布通知告知公眾，其被盜之「McGRATH™ MAC video laryngoscopes」不合格產品經非法販售一案，詳如說明段，請查照。

說明：

- 一、依據衛生福利部食品藥物管理署112年11月1日FDA器字第1121610323號函辦理。
- 二、案係美敦力總公司發布通知告知公眾，未經其授權的公司透過各種社群媒體平台非法出售被盜的旨揭產品不合格品。經查，涉案產品為「美敦力 麦格拉斯電子式影像喉頭鏡(未滅菌)」(衛部醫器輸壹字第021890號)(英文品名：Medtronic McGRATH MAC Video Laryngoscope (Non-sterile))，受影響型號為301-000-000，序號如附件。
- 三、前述被盜產品為不合格品，不應使用。美敦力總公司正在與美國食品藥物管理局(FDA)等單位合作，並採取行動追回被盜的不合格品。
- 四、有關案內醫療器材安全及品質警訊，載於衛生福利部食品藥物管理署全球資訊網站(<http://www.fda.gov.tw>)首頁>業務專區>通報及安全監視專區>醫療器材專區>安全及品質警訊>美敦力 麦格拉斯電子式影像喉頭鏡(未滅菌)回收警訊(國內無進口受影響產品)。

五、請協助轉知所屬會員或相關機構業者，以維護民眾安全及權益。

六、隨函檢附美國FDA回收警訊及受影響產品序號如附件。

正本：宜蘭縣醫師公會、宜蘭縣藥師公會、宜蘭縣藥劑生公會、宜蘭縣西藥商業同業公會、宜蘭縣商業總會、宜蘭縣各醫院

副本：本局食品藥物管理科

局長徐迺維

食品藥物管理科科长莊淑姿決行

本案依分層負責規定授權決行



COMPANY ANNOUNCEMENT

Medtronic Notification of Stolen Defective Products – Potentially Defective McGRATH™ MAC Video Laryngoscopes

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

[Read Announcement](#)
[View Product Photos](#)

Summary

Company Announcement Date:

September 28, 2023

FDA Publish Date:

October 19, 2023

Product Type:

Medical Devices

Reason for Announcement:

Stolen Potentially Defective

Company Name:

Medtronic

Brand Name:

Medtronic

Product Description:

McGRATH MAC video laryngoscopes

Company Announcement

NOTE: McGRATH™ MAC video laryngoscopes purchased directly from Medtronic or via its authorized distributors are not affected by this safety notice.

September 28, 2023– Medtronic is issuing this notification to inform the public of stolen defective McGRATH™ MAC video laryngoscopes that have been offered for sale illegally by unauthorized third parties through various social media platforms. These affected products did not pass Medtronic's rigorous quality tests established for the product, were not released for sale, distribution, or importation and were designated for destruction. These affected products are defective and should not be used. Medtronic is working closely with regulatory authorities and law enforcement organizations to help ensure that unauthorized advertisements are being removed as identified, and actions to recover the stolen defective products are underway.

The McGRATH™ MAC video laryngoscope is a device used to facilitate intubation of the trachea. The use of a defective McGRATH™ MAC video laryngoscope may result in patient harm, including failed laryngoscopy and/or intubation, potentially resulting in respiratory failure (including hypercarbia), hypoxia (leading to bradycardia, dysrhythmias), hypercapnia, tissue damage/tissue trauma and/or a delay to treatment (prolonged procedure/extended hospitalization).

A population of products affected by this notice (Item Code 301-000-000) are marked with the serial numbers listed below. Additionally, any McGRATH™ MAC video laryngoscopes without a serial number marked on the device are affected by this notice. The stolen defective products are not packaged in the labeled packaging containers shown below:

CONFORMING devices can be identified by the presence of serial number and packaged in either version of container shown.

Patient safety remains at the core of the Medtronic Mission to alleviate pain, restore health, and extend life. Medtronic urges healthcare professionals to purchase products only from trusted and reliable sources, such as directly from Medtronic or its authorized distributors. To find an authorized distributor or to purchase directly from Medtronic, contact Customer Service at

800-962-9888, Option 2.

Medtronic will continue to work closely with regulatory authorities and law enforcement agencies toward resolution of this issue. Anyone with information regarding the promotion or sale of potentially stolen products are encouraged to contact Medtronic Customer Service at 800-962-9888, Monday through Friday from 8AM to 7PM ET.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online \(/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda\)](/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)
- Regular Mail or Fax: [Download form \(/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting\)](/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

See List of [Medtronic Stolen Defective Product List \(/media/173190/download?attachment\)](/media/173190/download?attachment)

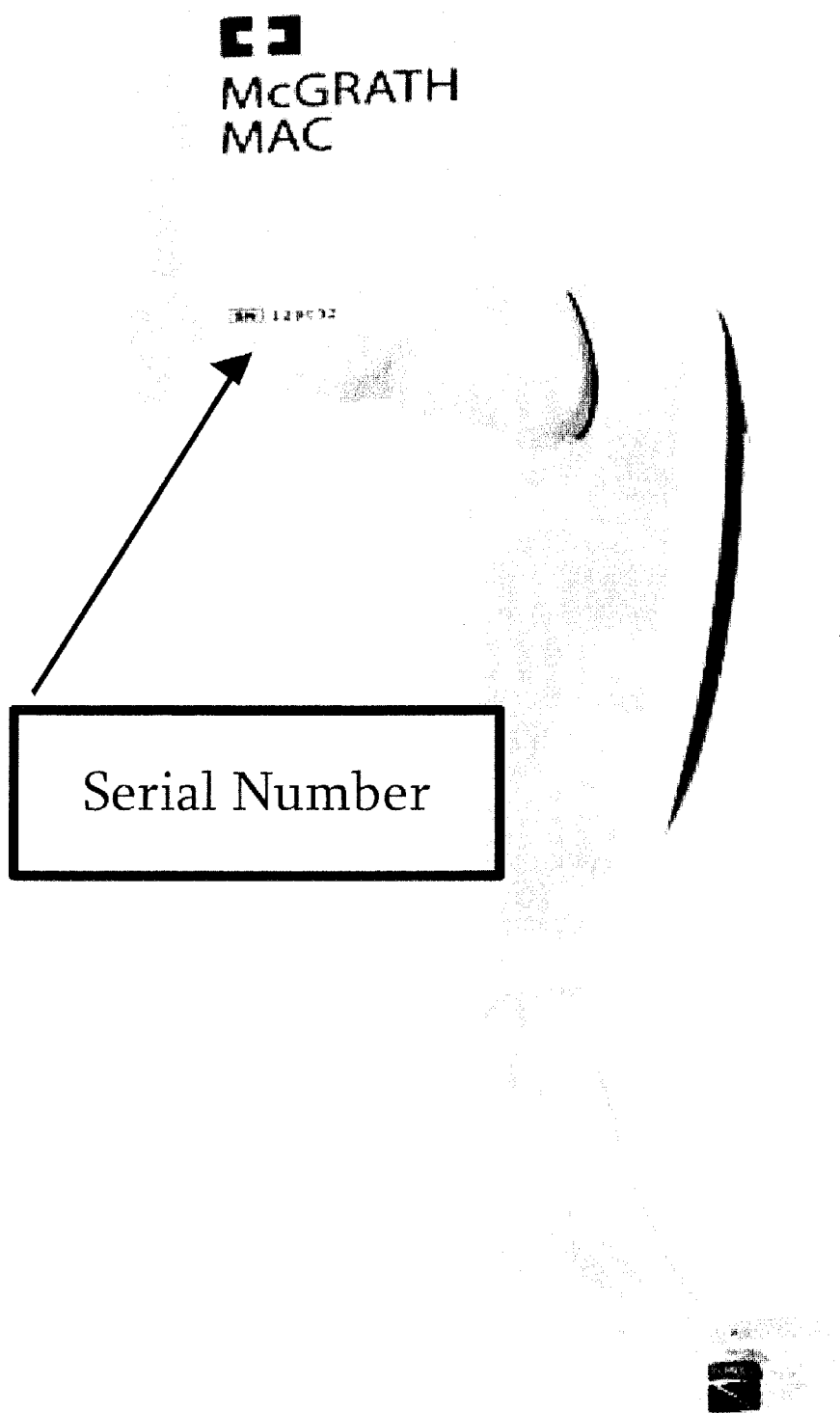
Company Contact Information

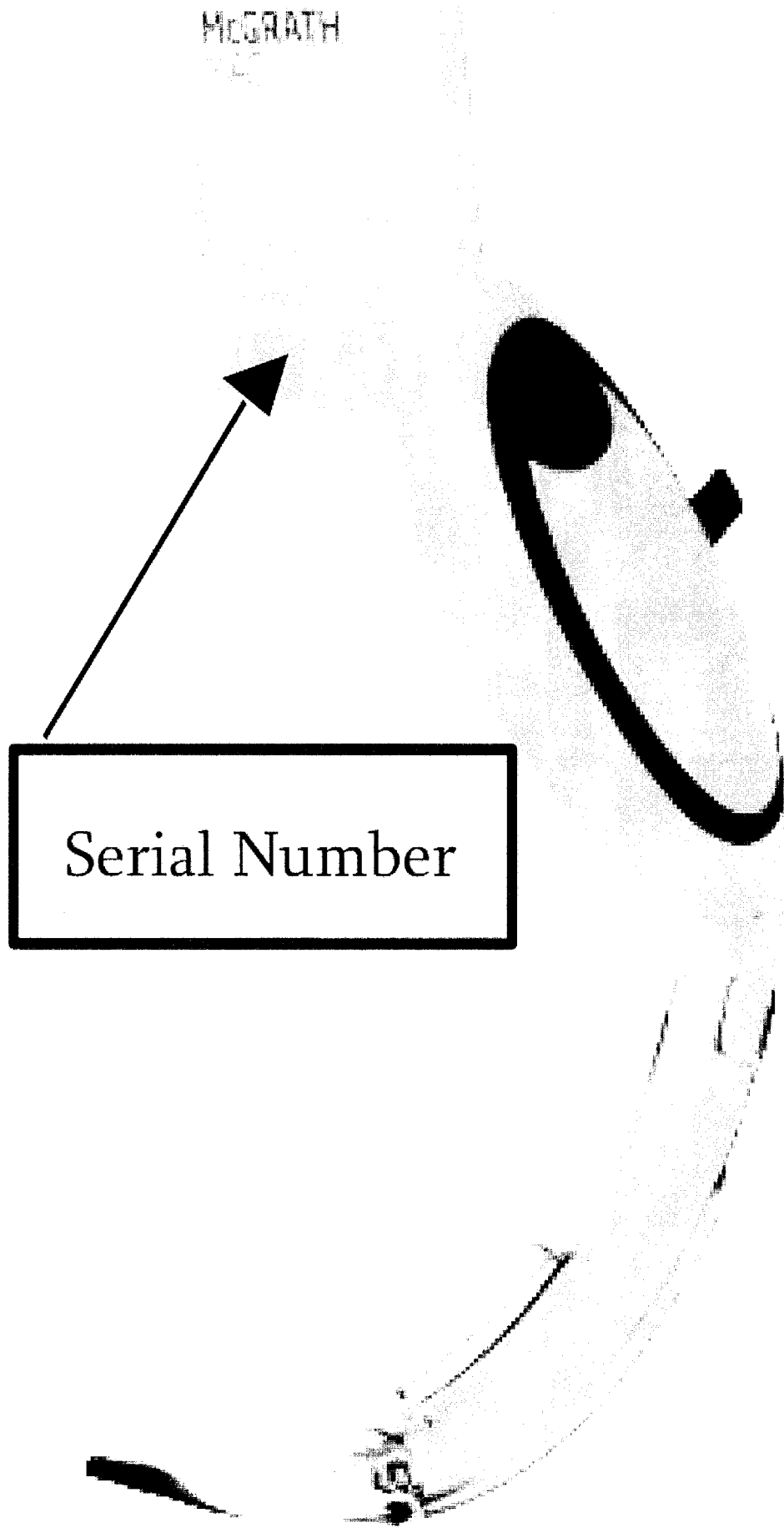
Consumers:

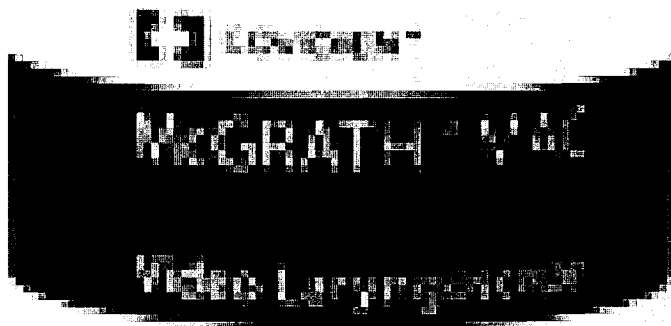
Medtronic Customer Service

📞 800-962-9888

Product Photos







McGRATH™

MAC

Video Laryngoscopes

RECALL

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[Safety Alerts \(/safety/recalls-market-withdrawals-safety-alerts\)](/safety/recalls-market-withdrawals-safety-alerts)

Serial Number									
000063	000677	001629	003191	004912	101048	101996	103596	105062	106061
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000085	000752	001669	003288	004942	101050	101998	103672	105071	106087
000092	000753	001760	003464	004960	101053	101999	103684	105075	106108
000093	000760	001826	003678	004965	101058	102000	103711	105106	106109
000112	000764	001829	003693	004975	101065	102001	103835	105225	106117
000120	000769	001859	003720	004976	101120	102002	103900	105303	106139
000121	000781	001952	003733	100010	101158	102003	103921	105325	106213
000146	000809	001985	003889	100012	101182	102011	104155	105341	106225
000153	000810	002008	003957	100015	101229	102140	104164	105363	106226
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000197	000879	002151	004444	100235	101452	102594	104428	105412	106308
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000224	000891	002174	004525	100256	101513	102676	104444	105432	106310
000233	000913	002197	004532	100264	101529	102693	104460	105434	106311
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Serial Number									
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Serial Number								
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122964	123415	123985	124491	125092	125572	126065	126890	
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122976	123450	123996	124508	125129	125582	126087	126906	
122979	123453	124011	124509	125137	125583	126115	126909	
122984	123460	124012	124510	125142	125589	126134	126926	
122994	123463	124021	124524	125147	125605	126185	126930	
123031	123464	124025	124537	125154	125613	126235	126970	
123033	123476	124032	124538	125176	125633	126238	127008	
123034	123504	124040	124583	125183	125634	126246	127164	
123046	123508	124047	124587	125184	125637	126267	127223	
123055	123519	124097	124588	125205	125654	126269	127329	
123093	123538	124100	124597	125232	125674	126272	127424	
123096	123543	124103	124605	125237	125685	126281	127719	