

PENGUMUMAN BAGI TUJUAN MENDAPATKAN MAKLUMBALAS BERKENAAN PERANTI PERUBATAN YANG TIDAK BERDAFTAR (*USANG, DIHENTIKAN DAN YATIM*) YANG MASIH BERFUNGSI/DIGUNAKAN DI FASILITI KESIHATAN.

Selaras dengan Perintah Peranti Perubatan (Pengecualian) 2024 [[Perintah Peranti Perubatan \(Pengecualian\) 2024](#)] yang mula berkuatkuasa pada 5 Mac 2024, perenggan 3 perintah telah menyatakan peranti – peranti perubatan usang, dihentikan, dan yatim adalah dikecualikan daripada keperluan pendaftaran di bawah Seksyen 5 Akta Peranti Perubatan (Akta 737). Walaubagaimanapun, pengecualian tersebut adalah tertakluk kepada syarat seperti mana yang dinyatakan dalam perenggan 3(2)(b) yang memberikan suatu punca kuasa kepada Pihak Berkuasa Peranti Perubatan (MDA) untuk menguruskan pengecualian pendaftaran peranti perubatan tersebut.

Objektif Pengumuman.

Pengumuman ini bertujuan untuk mendapatkan maklumbalas daripada pihak yang berkepentingan (pihak pengguna di fasiliti kesihatan) mengenai peranti perubatan yang masih berfungsi/digunakan, namun tidak lagi memenuhi syarat pendaftaran di bawah **Akta Peranti Perubatan 737**.

Pihak yang berkenaan diminta untuk memberikan maklumbalas mengenai peranti perubatan tersebut dengan melengkapkan borang maklumbalas sebelum / pada 30 April 2025, melalui pautan berikut :

Borang maklumbalas – Peranti perubatan tidak berdaftar (pendaftaran tidak aktif) tetapi masih berfungsi di fasiliti ;

<https://docs.google.com/forms/d/1tHq6fkbyyu0tEcb6Zalck5Fhhz3rlzHu1NbLX8jIXQg/preview>

Makluman dan kerjasama dari pihak tuan/puan amat kami hargai dan didahului dengan ucapan terima kasih.

Sekian, terima kasih.

Untuk sebarang pertanyaan, sila hubungi no berikut ;

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ANNOUNCEMENT FOR THE PURPOSE OF OBTAINING FEEDBACK REGARDING UNREGISTERED MEDICAL DEVICES (OBSOLETE, DISCONTINUED, AND ORPHANED) THAT ARE STILL FUNCTIONING/USED IN HEALTHCARE FACILITIES.

In line with the Medical Devices (Exemption) Order 2024 [[Medical Device \(Exemption\) Order 2024](#)] which comes into force on 5th March 2024, paragraph 3 of the order states that obsolete, discontinued, and orphaned medical devices are exempted from the registration requirements under Section 5 of the Medical Devices Act (Act 737). However, this exemption is subject to conditions as stated in paragraph 3(2)(b), which provides authority to the Medical Device Authority (MDA) to manage the registration exemption of these medical devices.

Objective of the Announcement.

This announcement aims to obtain feedback from stakeholders (users in healthcare facilities) regarding medical devices that are still functioning/being used but no longer meet the registration requirements under the Medical Devices Act 737.

Relevant parties are requested to provide feedback regarding these medical devices by completing the feedback form before/on 30th April 2025, through the following link:

Feedback Form – Unregistered medical devices (inactive registration) but still functioning in facilities;
<https://docs.google.com/forms/d/1tHq6fkbyyu0tEcb6Zalck5Fhhz3rlzHu1NbLX8jIXQg/preview>

We highly appreciate your attention and cooperation, thank you in advance.
Thank you.

For related inquiries, please contact the following number ;

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