

香港特別行政區政府
衛生署
醫療儀器科

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THE GOVERNMENT OF THE HONG KONG
SPECIAL ADMINISTRATIVE REGION
DEPARTMENT OF HEALTH
MEDICAL DEVICE DIVISION

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By mail and e-mail

11 July 2024

Dr. Lydia LEUNG
Chairlady
Hong Kong Medical and Healthcare Device Industries Association
Room 4, Unit 601
Core Building 1
Hong Kong Science Park
Pak Shek Kok
New Territories
Hong Kong

Dear Dr. LEUNG,

**Key dates of rollout of e-services of
Medical Device Information System (MDIS) have been updated**

Thank you for your unwavering support of the new e-services launched as part of the Medical Device Information System (MDIS) since April 2, 2024. We greatly appreciate the valuable feedback and insights provided by local responsible persons (LRPs) and traders during this transition.

After carefully considering the comments and requests received, we have made the decision to postpone the rollout of the remaining MDIS e-services. This change is in direct response to the need for users to have more time to become fully acquainted and familiar with the new electronic systems.

The revised key dates for the rollout of the MDIS e-services, as well as the corresponding phasing out of paper-based submissions, are outlined in the attached Annex. Please note that we will continue to review these dates and provide updates on the MDIS Theme page as necessary.

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We thank you for your patience and understanding as we work to ensure a smooth transition to the MDIS e-services. Your continued support and partnership are invaluable as we optimize the outcome of this important initiative for the benefit of the industry.

Should you require any assistance, please do not hesitate to contact our dedicated MDIS technical support team at 3702 5356 or via email at mdis_support@nexify.com.hk. For general inquiries regarding applications under MDACS, please reach out to the Medical Device Division of the Department of Health at 3107 8484 or via email at mdd@dh.gov.hk.

We look forward to your ongoing collaboration as we work to make the MDIS e-services a resounding success.

Thank you once again for your unwavering support.

Yours faithfully,



(Dr. Addi CHAN)
for Director of Health

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Annex: Updated key dates of rollout of e-services of MDIS

Launch date	E-Service	Phase-out date of paper-based submissions
2 April 2024	<ul style="list-style-type: none"> Account Registration 	
15 April 2024	<ul style="list-style-type: none"> Application for the Listing of Class II/III/IV General Medical Devices (MD101) Application for the Listing of In Vitro Diagnostic Medical Devices (IVDMD) (MD102) Application for Inclusion on the List of Importers/Distributors (MD-IP+D) Application for the Listing of Local Manufacturers (LM) 	17 June 2024
15 July 2024 September 2024	<ul style="list-style-type: none"> Change Application for Listed Medical Devices Takeover Application for Listed Medical Devices Renewal Application for Listed Medical Devices Renewal and Change Application for Listed Importers/Distributors Renewal and Change Application for Listed Local Manufacturers Medical Device Adverse Event Report Form – for Medical Device Users Medical Device Adverse Event Report Form – for Local Responsible Persons Medical Device Safety Alert Report Form 	16 September 2024 31 December 2024
14 October 2024 December 2024	<ul style="list-style-type: none"> Application for recognition under the Conformity Assessment Body (CAB) Recognition Scheme Application for certification to National Medical Products Administration (NMPA) 	14 October 2024 31 December 2024

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