

Industry Briefing

Concurrent CN

24 September 2026

Medical Devices Cluster
Health Sciences Authority (HSA)

What's Changing — Concurrent CN

Up to **2 CN applications** may now be processed concurrently for the same medical device listing



Regulatory update: 31 July 2026

Dear Medical Device Stakeholders,

As part of HSA's ongoing initiative to improve regulatory efficiency, the Medical Devices Cluster (MDC) is pleased to announce that, with immediate effect, up to two (2) Change Notification (CN) applications may now be processed concurrently for the same medical device listing. Previously, only one (1) CN application could be processed at a time for a medical device listing, which may have caused delays in implementing necessary changes to the medical device. This enhancement provides greater flexibility for stakeholders in managing regulatory changes while facilitating more timely implementation of updates to medical devices.

Stakeholders are advised to ensure that no more than two (2) active CN applications are ongoing for the same medical device listing at the point of submission. Where a CN application includes a listing that already has two (2) active CN applications at the point of submission, the application cannot be accepted for processing and will be rejected in its entirety. As application fees are non-refundable, stakeholders are encouraged to verify the status of existing CN applications and plan their submissions accordingly.

We would like to also take the opportunity to remind all stakeholders to provide a complete dossier per documentary requirements stated in GN-21 Guidance of Change Notification and update the device form in our online SHARE system accordingly at point of submission to facilitate timely processing of your applications.

Regards,

MEDICAL DEVICES CLUSTER
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY
SINGAPORE

What's Changing — Concurrent CN

Submission rule:

- ✓ Where a listing already has **2 active CN applications**, any new CN application for that listing will be rejected in its entirety
- ✓ Application fees are **non-refundable**. Always verify the status of existing CN applications before submitting
- ✓ Provide a complete dossier per **GN-21** documentary requirements, including updated Annex 2 summary of changes

MEDICAL DEVICE GUIDANCE

AUGUST 2026

Please select the correct box.

The change(s) in this Change Notification application is/are related to field safety corrective action and/or reportable adverse events.

☐ Yes ☐ No

R7 ► Is there an on-going Change Notification for listing(s) in this application.

☐ Yes ☐ No

If yes, job reference no.: _____

Note: At the point of submission, there can be no more than two (2) CN applications that are active for the same listing. A CN application will be rejected in its entirety if any listing within it already has two (2) active CN applications. There will be no refund of any fees paid. ◀

Industry Briefing

Premarket Submission Checklist for Medical Device Product Registration

24 September 2026

Medical Devices Cluster
Health Sciences Authority (HSA)

Our thanks to industry partners from APACMed and SMF

- A preliminary draft of the Premarket Submission Checklist was shared with industry reps for inputs
- 32 comments were received
- HSA made improvements and adjustments to the checklist based on the feedback
- This checklist in this form was shaped with industry input

Why Are We Introducing This?

Current challenges:

- Incomplete submissions are one of the most common causes of avoidable registration delays
- Missing documents or wrong folder uploads in SHARE prevent evaluation from starting
- This leads to repeated input requests, longer timelines, and delayed market access

What this means for industry:

- More back-and-forth communication
- Delays that are avoidable with a complete submission upfront
- Unpredictable timelines

Our objective:

- A self-check tool for dossier completeness to help you get it right the first time
- No delays from misplaced documents, upload to the correct SHARE folders from the start
- Faster progression to technical evaluation by reducing unnecessary IRs

What Is the Premarket Submission Checklist?

Checklist is a completeness confirmation tool:

- Complements and elaborates on existing requirements from GN-15, GN-17, GN-18 in a single document
- **No new regulatory requirements are introduced**
- Mapped to SHARE to assist companies to ensure documents are uploaded to the correct sections

Section	Content
Device Information	Device type, risk class, evaluation route, grouping
Sections 1–7	Administrative and descriptive documents (LOA, LOC, reference agency approvals, declarations, executive summary, EP checklist and DoC, device description)
Section 8	Design verification and validation
Section 9	Clinical evaluation report
Sections 10–12	Device labelling, risk management, manufacturing information
Section 13	Other supporting documents not covered by Sections 1–12

Upload Documents to the Correct SHARE Folders

- Documents must be uploaded to the correct SHARE folder/sub-folders
- Justification provided for Section 8, if not applicable
- Section 13 (Others) is **only for documents that do not fit in any other folders**
- Consider relevancy of documents to the submission before uploading to any section including Section 13 (Others)

SHARE Folder	Premarket Submission Checklist Section
1. Letter of Authorisation	Section 1
2. Annex 2 List of Configurations	Section 2
3. Proof of Reference Agency Approvals	Section 3
4. Declarations	Section 4
5. Executive Summary	Section 5
6. Essential Principles Checklist and DoC	Section 6
7. Device Description	Section 7
8. Design Verification and Validation (8.1–8.12)	Section 8 – Includes sub-folders for Biocompatibility, Sterilisation, Shelf Life, Software and so on
9. Clinical Evaluation Report	Section 9
10. Device Labelling (10.1–10.2)	Section 10 – Includes sub-folders for Primary and Secondary Labels and IFU
11. Risk Management	Section 11
12. Manufacturing Information (12.1–12.3)	Section 12 – Includes sub-folders for Name and address for manufacturing sites, ISO 13485 and so on
13. Others	Section 13 – Only for documents that do not fit in any of the above folders

- **Not a new requirement**
- Combines 2 declarations that are frequently left out of submissions

Declaration on Device Labelling, Adverse Events and Field Safety Corrective Actions (Published under GN-15 Annex 4)

- Consolidates the labelling declaration and AE/FSCA attestation into a single template
- Product owner declares on company letterhead
- Section 1: Labelling, packaging and IFU — identical or not identical to reference agency approval (applicable for Abridged, Expedited and Immediate routes)
- Section 2: AE and FSCA declaration or summary (applicable for all routes)

New Supporting Templates

Device Labelling, Adverse Events and Field Safety Corrective Actions Declaration Template

[To be printed on Company Letterhead of Product Owner]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

We, *[name of Product Owner (Company Name)]*, as the Product Owner for registration of the medical device(s) stated below, hereby declare the following under section 1 (if applicable) and section 2.

This declaration shall apply to the following medical devices:

[List containing product names of medical devices]

Section 1: Applicable for applications submitted under abridged, expedited and immediate evaluation routes

☐ We declare that the medical devices have labelling, packaging and Instructions for Use (IFU) of <device name> for sale in Singapore that are identical or not identical to that approved by <state the reference agencies> being used as the basis for Abridged/Expedited/Immediate <delete where applicable> evaluation route. If not identical, the description of the differences is declared in the table below.

Labelling/ packaging/ IFU approved by reference agency	Labelling/ packaging/ IFU submitted for registration in Singapore

Section 2: Applicable for all applications

[Indicate the applicable checkbox/ checkboxes]

☐ We declare that the medical devices have no reportable adverse events (AE) and field safety corrective actions (FSCA) since the product was introduced for commercial distribution, globally since <insert date specific to MM/YY> or in the last five years. This attestation is not restricted to usage only as intended by the product owner.

This is applicable to:

[List containing product names of medical devices]

☐ We declare that there were AEs reported and/ or FSCAs conducted for the following device(s)

- For AE(s)

AE description with impacted device name/ device identifier	Frequency of Occurrence (refers to the number of reports for the AE / total units distributed globally in the period of dd/mm/yyyy to dd/mm/yyyy)

- For FSCA(s)

Date of FSCA	Reason for FSCA with impacted device name/ identifier	Countries where FSCA was conducted	Status of FSCA (open/ closed)	Summary of CAPA/ CAPA effectiveness for FSCAs with open status ONLY

Yours sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Name and address of company]

New Supporting Templates

Section 2 of the Checklist – Annex 2 List of Configurations

Enhancement:

- For applications containing **implants**, please fill-up the "**List of configuration (Implant)**" tab. The additional columns (labels, IFU, Australia TGA, Health Canada, Japan MHLW, US FDA, EC Certificate, EU DOC, Biocompatibility, Sterilization Validation, Shelf life Report, Bench test) to list the filenames in this tab is applicable to all models, including the accessories in the List of Configuration

Reminders:

- Do not include Class A devices or non-medical device
- For **devices involving software**, please indicate the software version to be supplied in Singapore under the "Brief Description of Item" column. Please note that the exact software version (e.g. down to tracking of bug fixes) should be provided

Premarket Submission Checklist applies to the following applications:

- Class B, C and D premarket applications submitted through Full (F), Abridged (A), Expedited (E) evaluation routes submitted **from 1 October 2026** onwards
- Completed Premarket Submission Checklist must be included with every submission

The Premarket Submission Checklist does not apply to the following applications (Not required to be submitted):

- Class B, C and D premarket applications submitted through Full (F), Abridged (A), Expedited (E) evaluation routes submitted **before 1 October 2026**
- All IBR / ICR applications or Change Notification applications

What Makes a Submission Incomplete?

The following are common causes of an incomplete submission (non-exhaustive):

Common Mistake	How to Avoid It
Premarket Submission Checklist not submitted or only partially filled in	Complete the checklist in full and include it with every submission
Required SHARE folders are empty with no documents uploaded	Ensure all applicable SHARE folders have the relevant documents uploaded before submitting
Documents uploaded to the wrong SHARE folder (e.g. sterilisation report in Biocompatibility folder)	Follow the checklist-to-folder mapping — each section corresponds to a specific SHARE folder
Placeholder or blank files uploaded	Only upload final, complete documents — no "to be provided later" files
Annex 2 List of Configurations • does not tally with SHARE (e.g. wrong number of models, different identifiers) • file mapping not submitted for entire implant system (including accessories)	Cross-check Annex 2 against your SHARE uploads before submitting
Section 8 folders left empty with no explanation	Upload relevant documents or provide justification in the checklist if not applicable
Section 13 (Others) used as a catch-all folder. Documents uploaded to Section 13 when an appropriate SHARE folder exists	Only use Section 13 for documents that are required to support the registration and genuinely do not fit any other folder

Grace Period:

- Incomplete submissions will not be rejected during this period

Enforcement:

- Incomplete submissions will not be accepted for evaluation. Application will be rejected and **no exceptions will be granted**

Grace Period:
1 October to
31 December 2026

Enforcement:
From 1 January 2027

What to Expect: October 2026 Onwards

Grace Period	From 1 Jan 2027
Incomplete submission* found • HSA notifies you of deficiencies via input request • Your application will continue to be processed	Incomplete submissions* will be rejected • No exceptions will be granted • No input requests will be sent • No refund of application fees • Companies to resubmit with a new, complete application

The grace period to support you through the transition

Make the most of the grace period

- Familiarise your team with the checklist and SHARE folder structure
- Use the checklist to refine your internal dossier preparation process

* Refer to Slide 10 for what constitutes an incomplete submission

- The Premarket Submission Checklist consolidates existing requirements — no new regulatory requirements are introduced
- Use the grace period (1 Oct – 31 Dec 2026) to test and refine your internal dossier preparation process
- Key Requirement: Upload documents to the correct SHARE folders
- Provide justification in Section 8 of checklist if certain studies are not applicable
- Incomplete submissions will be rejected from 1 January 2027 — no exceptions, no input requests, no refund of application fees
- Premarket Submission Checklist and updated Annex 2 LOC will be published after the briefing, and details will be shared via email

FAQ

Concurrent Change Notification

Q: How many change notification (CN) applications that affect device form fields may be submitted concurrently for the same device listing?

A: From 31 July 2026, applicants may have up to two active CN applications for the same device listing at any one time, regardless of the change type.

However, only one of the two applications may involve amendments to the device form fields. Applicants are encouraged to plan the scope and sequence of their changes before submission. Where multiple upcoming changes affect product information in SHARE, applicants may consolidate the changes into a single CN application or submit the subsequent CN application after the earlier application is completed.

Notification CNs may also be bundled and submitted to HSA within six months of the first global implementation.

Q: Will SHARE prevent the submission of a third CN application, and how can applicants track active CN applications?

A: SHARE will not prevent the submission of a third or subsequent CN application. However, any CN application submitted while two CN applications are already active for the same device listing will be rejected in its entirety. Applicants should therefore check the number of active applications for the device listing before making further submission.

To check the active CN applications, navigate to **Products > Class B/C/D** in SHARE, search for and open the relevant device listing, and review the applications under **Related Applications**.

Q: Can multiple changes be included in a single CN application?

A: Yes. Multiple changes may be consolidated into a single CN application, in accordance with the guidelines set out in GN-21. The introduction of concurrent CN processing does not change the existing GN-21 processes or requirements. Where an application includes changes from different categories, the applicable fee will be based on the highest category of change selected.

Q: Is approval of the second CN application dependent on approval of the first?

A: Where the changes in the two applications are independent, each application may generally be processed independently. Where there are dependencies between the applications, the processing or approval of one application may depend on the other, and this will be assessed on a case-by-case basis.

Q: For a CN application involving changes to device form fields, may the device form be amended only when the application is ready for approval?

A: No. The device form in SHARE should be updated at the time of submission so that the application reflects the proposed changes from the outset, and to facilitate timely processing of the application.

Premarket Submission Checklist

1. SHARE submission and document filing

Q: Where should the pre-market submission checklist be uploaded in SHARE?

A: The pre-market submission checklist should be uploaded under Section 13 – Others in SHARE.

Q: Where should physical and mechanical testing reports be submitted in SHARE?

A: Mechanical testing reports for general medical devices should be submitted under Section 8.9 – Bench Testing.

2. Dossier completeness and document availability

Q: Is a submission considered incomplete if only accelerated ageing data are available and the real-time ageing study is still ongoing?

A: No. The submission will not be considered incomplete if an accelerated ageing stability study has been submitted under Section 8.3 of the checklist.

Q: What should an applicant do if a document or requirement is not applicable to the medical device?

A: The applicant should indicate the non-applicability and provide the relevant justification in the pre-market submission checklist.

Q: How should documents that will be provided directly to HSA by a third party be indicated in the checklist?

A: The applicant should indicate in the relevant justification field of the checklist that Third Party Access is required.

3. Templates and declarations

Q: Is the Annex 4 declaration template in GN-15 mandatory?

A: Yes. Annex 4 – Device Labelling, Adverse Events and Field Safety Corrective Actions Declaration Template to GN-15 must be used.

4. Incomplete submissions, rejection and fees

Q: What does “no refund of application fees” refer to?

A: This refers to the application fee for device registration stated on our [website](#) .

Q: Will applicants be notified if an application is rejected due to an incomplete submission?

A: Yes. From 1 January 2027, applicants will receive a system-generated email notification. The officer will also communicate the identified deficiencies.