HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

October 2025

MEDICAL DEVICE GUIDANCE

GN-34: Guidance Document for IVD Analysers

Revision 2

HSA Health Sciences Authority

CONTENTS

1. INTRODUCTION 4
1.1. Purpose 4
1.2. Background 4
1.3. Scope 4
1.4. Definitions 5
2. RISK CLASSIFICATON OF IVD ANALYSERS 8
3. DEVICE-SPECIFIC 'FAMILY' GROUPING CRITERIA FOR IVD ANALYSERS 10
4. SMDR Listing Options FOR CLOSED-SYSTEM IVD ANALYSERS 12
4.1. SMDR Listing Options for New Closed-System Analyser(s) 13
4.2. Product Registration of Closed IVD SYSTEMs which do not have Analyser(s) Currently Listed on SMDR in SPLIT IVD Analyser Device Listing(s) 14
4.3. Product Registration of IVD Test Kits which have Compatible Closed-System IVD Analyser(s) Listed on SMDR in SPLIT IVD Analyser Device Listing(s) 16
5. CHANGE NOTIFICATION APPLICATIONS 18
5.1. Addition of Analyser to a Device Listing 18
5.2. Changes to IVD Analysers 20
5.3. Changes to the List of Compatible IVD Reagent Kits for SPLIT IVD Analyser Device Listings 21
6. SPLIT ANALYSER LISTING OPTION FOR REGISTERED IVD SYSTEMS ON THE SMDR 22
ANNEX 1 24
ANNEX 2 26

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors.

REVISION HISTORY

Guidance Version (Effective Date) *[3 latest revisions]*	Revision
GN-34: Revision 1 (01 Dec 2017)	R1
R1.1 ► GN-34: Revision 1.1 (01 Jun 2018)	R1.1
R1.2 ► GN-34: Revision 1.2 (19 Sep 2018)	R1.2
R1.3 ► GN-34: Revision 1.3 (17 Feb 2020)	R1.3
R2 ► GN-34: Revision 2 (21 Oct 2025)	R2

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

1. INTRODUCTION

1.1. Purpose

This document provides guidance to product owners and registrants concerning *in vitro* diagnostic devices (IVD) analysers and their associated accessories.

1.2. Background

HSA has made updates for IVD analysers concerning their risk classification, grouping, listing options on the Singapore Medical Device Register (SMDR) and Change Notification (CN) for all listings containing IVD analysers.

1.3. Scope

This guidance document addresses the following for IVD analysers:

- Risk classification
- Grouping of medical devices for product registration
- Product registration and SMDR listing options
- Change Notification

The affected guidance documents are as follows:

Affected Guidance	Title
GN-12-1	Guidance on Grouping of Medical Devices for Product Registration – General Grouping
GN-12-2	Guidance on Grouping of Medical Devices for Product Registration – Device Specific Grouping Criteria
GN-14	Guidance on the Risk Classification of *In Vitro* Diagnostic Medical Devices
GN-15	Guidance on Medical Device Product Registration
GN-21	Guidance on Change Notification for Registered Medical Devices
GN-22	Guidance for Dealers on Class A Medical Devices Exempted from Product Registration

Analysers that are not manufactured, sold or represented by manufacturers for use in IVD applications are not considered to be IVDs. This includes products sold for general laboratory applications and products that are labelled 'For Research Use Only' (RUO).

1.4. Definitions

Definitions that do not indicate they are set out in the Health Products Act (A*ct*) and Health Products (Medical Devices) Regulations 2010 (*Regulations*) are intended as guidance in this document. These definitions are not taken verbatim from the above legislation and should not be used in any legal context. These definitions are meant to provide guidance in layman terms.

ACCESSORY: R1.3 ► for the purposes of this guidance document, means an article that is intended specifically by its product owner to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended purpose. An accessory is typically intended to be

used for one or more of the purposes as described in the definition of medical device and therefore should be considered a medical device. ◄

INTENDED PURPOSE/INTENDED USE *(as set out in the Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

IN VITRO DIAGNOSTIC (IVD) PRODUCT *(as set out in the Regulations)*:

R1.3 ► means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information –

- Concerning a physiological or pathological state or a congenital abnormality;
- to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or
- to monitor therapeutic measures; and

includes a specimen receptacle ◄

IVD ANALYSER: IVD analysers are equipment intended to be used with IVD reagents so as to allow the IVD reagents to achieve their intended use. IVD analysers are typically instruments that analyse the reaction and yield a result of positive, negative, amount of analyte detected, etc.

PRODUCT OWNER *(as set out in the Regulations)*: in relation to a health product, means a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

PROPRIETARY NAME: for the purposes of this guidance document, a unique name given by the product owner to identify a medical device as a whole product, also known as the trade name or brand name.

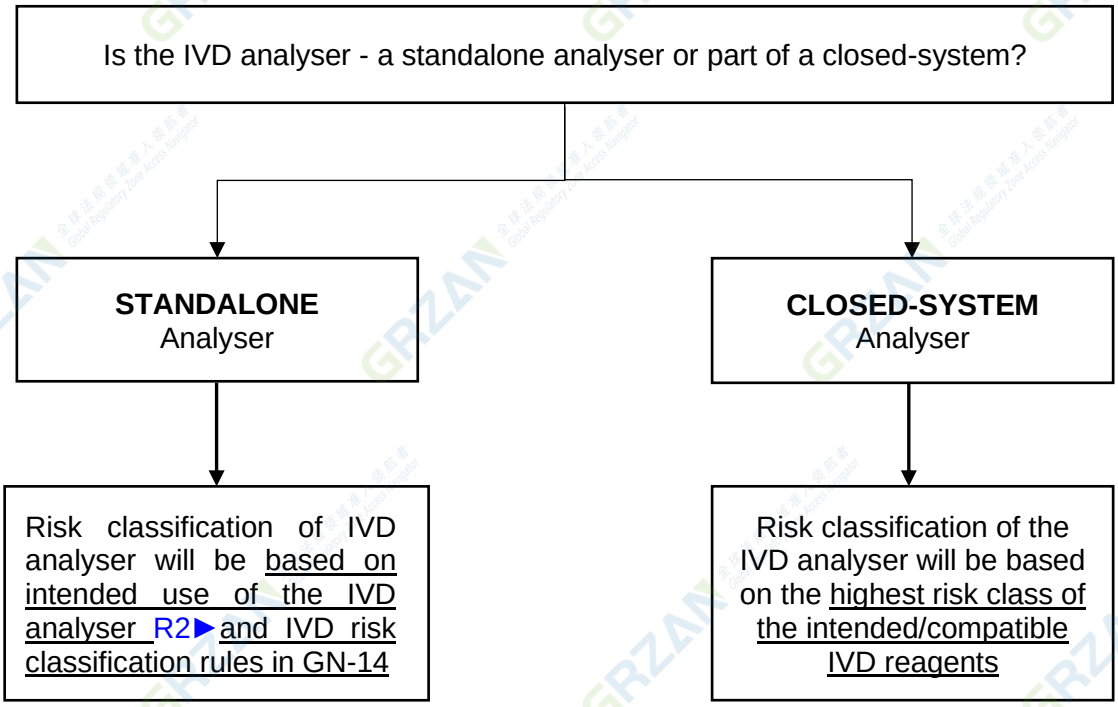
2. RISK CLASSIFICATON OF IVD ANALYSERS

The risk classification of an IVD analyser (inclusive of software) depends on the intended purpose of the analyser and whether it is intended to be used as a standalone analyser or as part of a closed IVD system.

Standalone analysers are instruments that are not intended by their product owners to be used with specific reagents. Typically, these instruments can be used with reagents from different product owners.

Closed-system analysers are instruments that are intended by their product owners to be used with specific reagents, which typically come from the same product owner. Refer to Flowchart 1 for the risk classification of IVD analysers.

Flowchart 1: Risk Classification approach for of IVD Analysers



Example of the risk classification for a closed-system analyser:
IVD reagents X, Y and Z have different intended uses and the highest risk class among them is Class C. All 3 reagents are compatible and intended for use with IVD analyser P. Therefore, IVD analyser P is a closed-system analyser and its risk class shall be Class C.

Example of the risk classification for a standalone analyser:
IVD analyser Q is used for the automation of an enzyme immunoassay. The product owner does not intend for the analyser to be used with specific reagents; and its labels and user manual do not indicate the performance characteristics of any reagents using the automated protocol of the analyser. Therefore, IVD analyser Q is a standalone analyser and its risk class shall be Class A as per GN-14 Rule 5.

R2 ► Refer to GN-14 Guidance on the Risk Classification of *In Vitro* Diagnostic Medical Devices for further example and rationale on the risk classification of IVD analysers under Rule 5. ◄
R2 ► -- ◄

3. DEVICE-SPECIFIC 'FAMILY' GROUPING CRITERIA FOR IVD ANALYSERS

IVD analysers that meet the 'FAMILY' grouping criteria indicated in GN-12-1 Guidance on Grouping of Medical Devices, may be grouped together under one device listing on SMDR if they also fulfil the additional grouping requirements of the list of permissible variants as shown in Table 2 below. The non-permissible variants are also specified in Table 1.

R2 ► -- ◄

Table 1: List of Permissible and Non-permissible Variants for 'FAMILY' Grouping of IVD Analysers

Permissible Variants	Non-Permissible Variants
1. Features that do not impact the diagnostic function • throughput • differences in user interface • printing function • wireless capability • software version • sample volume • On-board stability • calibration frequency	1. Features that impact the diagnostic function or lead to different specifications for their compatible reagent kits, for example but not limited to: • sensitivity • specificity • linearity • measuring range 2. Methodology / assay principles

Refer to Flowchart 2 for the decision flowchart on 'FAMILY' grouping of IVD analysers under a single device listing.

Flowchart 2: Decision Flowchart on 'FAMILY' Grouping of IVD Analysers under one Device Listing on SMDR



4. SMDR LISTING OPTIONS FOR CLOSED-SYSTEM IVD ANALYSERS

For relevant scenarios encountered for pre-market product registration applications, refer to the following sections below:

R1.3 ►

- Section 4.1: SMDR listing options for new closed-system analyser(s)
- Section 4.2: Product registration of closed IVD SYSTEMs, which **do not have** analyser(s) currently listed on SMDR in **SPLIT** IVD analyser device listing(s)
- Section 4.3: Product registration of IVD test kits, which have compatible closed-system analyser(s) currently listed on SMDR in their own **SPLIT** IVD analyser device listing(s) ◄

Note: Section 4.3 does not apply to analysers listed as part of another IVD system on the SMDR.

4.1. SMDR Listing Options for New Closed-System Analyser(s)

Two SMDR listing options are available for closed-system IVD analysers, which are submitted for pre-market registration together with their compatible IVD test kits and reagents as an IVD SYSTEM.

- **Option 1 (IVD SYSTEM Listing)**: Listing of analysers together with its compatible IVD reagents

Note: Closed-system IVD SYSTEMS listing per GN-12-1

- **Option 2 (SPLIT IVD Analyser Device Listing)**: Listing of the IVD analysers separately from the compatible IVD reagents. The IVD analyser may be listed on its own, or with other IVD analysers that meet the 'FAMILY' grouping criteria. (Refer to Section 3 of this guidance for more information.)

Note: Option 2 will incur additional annual (risk-class based) registration retention fee for the SPLIT LISTING of analysers. Analyser accessories such as cleaning solutions and bulk reagents may be listed with the analyser.

R2 ► When Option 2 is selected, the compatible reagent(s) will be listed as a reagent only listing while the analyser is split listed. The analyser will not be able to be listed as a closed system with any other reagents. ◄

Upon selecting one of the two listing options, change to the other listing option is not permitted.

4.2. Product Registration of Closed IVD SYSTEMs which do not have Analyser(s) Currently Listed on SMDR in SPLIT IVD Analyser Device Listing(s)

Product registration requirements remain unchanged for closed-system analysers which are submitted together with their compatible IVD test kits and reagents for pre-market registration as an IVD SYSTEM. However registrants should refer to Section 4.1 of this Guidance and inform HSA of their selected listing option.

The following options are available to Registrants who select Option 2 (**SPLIT IVD Analyser Device Listing**). The closed-system IVD analyser(s) may be listed in:

A. A **NEW** IVD analyser listing; OR
B. An **EXISTING** IVD analyser listing for which the FAMILY grouping criteria is fulfilled

R2 ► Registrants who choose to add the new closed-system IVD analyser(s) to an **EXISTING** IVD Analyser listing, are required to submit a Change Notification application for the **EXISTING** IVD analyser listing after approval of the IVD SYSTEM product registration application.

The Change Notification should be submitted under category 'Other Notification Changes (Verified by HSA prior to submission)', together with the following supporting documents:

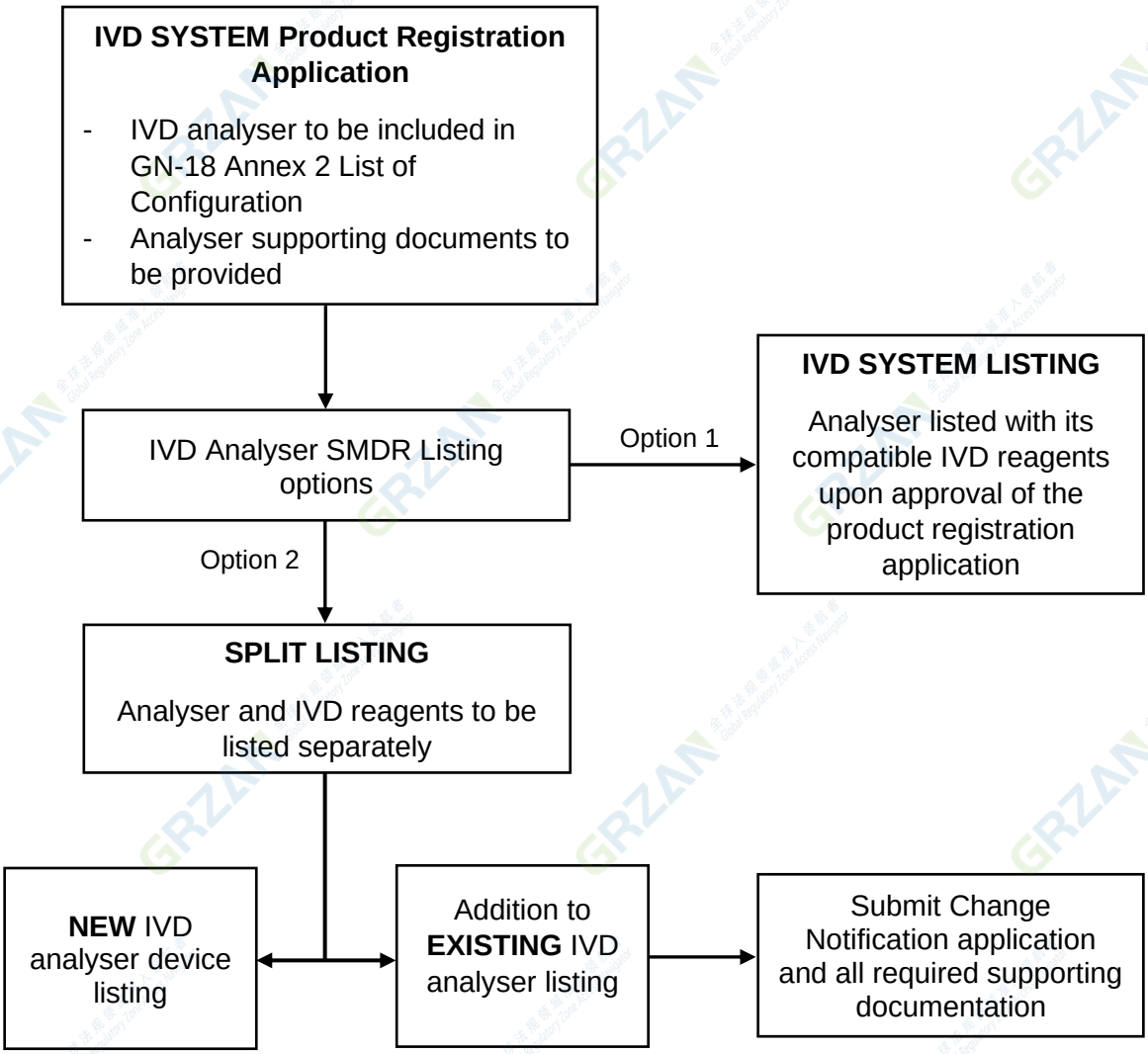
- A copy of the confirmation email from HSA on the eligibility to add the new IVD analyser(s) to an existing IVD Analyser listing. This document is to be uploaded into this folder in SHARE: "Supporting Documents > Email Correspondence with HSA"
- GN-34 Annex 2 List of compatible reagents with analysers in SPLIT IVD analyser device listings
- GN-21 Annex 2 Summary Table of Change Notification

- GN-18 Annex 2 List of Configurations with the new analyser model(s) highlighted

Applicants should state IVD SYSTEM pre-market application reference number within the submitted GN-21 Annex 2 Summary Table of Change Notification. ◄

Refer to Flowchart 3 for an overview on the workflow.

Flowchart 3: Product Registration Workflow for Closed IVD SYSTEMs which do not have Analysers Listed on SMDR in a **SPLIT** IVD Analyser Listing(s)



4.3. Product Registration of IVD Test Kits which have Compatible Closed-System IVD Analyser(s) Listed on SMDR in SPLIT IVD Analyser Device Listing(s)

For product registration of IVD test kits that have a compatible closed-system analyser already listed in its own analyser device listing, applicants can exclude the closed-system analyser from GN-18 Annex 2 List of Configurations. Submission of pre-market registration supporting documents for the IVD analyser is also not required.

The following approach would be applicable instead:

(A) When there are no changes to analyser specifications (inclusive of analyser software), labels and user manual as compared to the registered IVD analyser:

- Registrants are to submit the declaration for registered IVD analysers in SPLIT IVD analyser device listings (Refer to Annex 1 for declaration template)
- Registrants are to submit a Change Notification application for the affected analyser device listing, to update the list of registered reagents that are compatible and intended for use with the listed analyser (R1.3 ► Refer to Section 5.3 of this guidance for more information◄)

(B) When there are changes to the currently approved analyser specifications (inclusive of analyser software), labels and user manual:

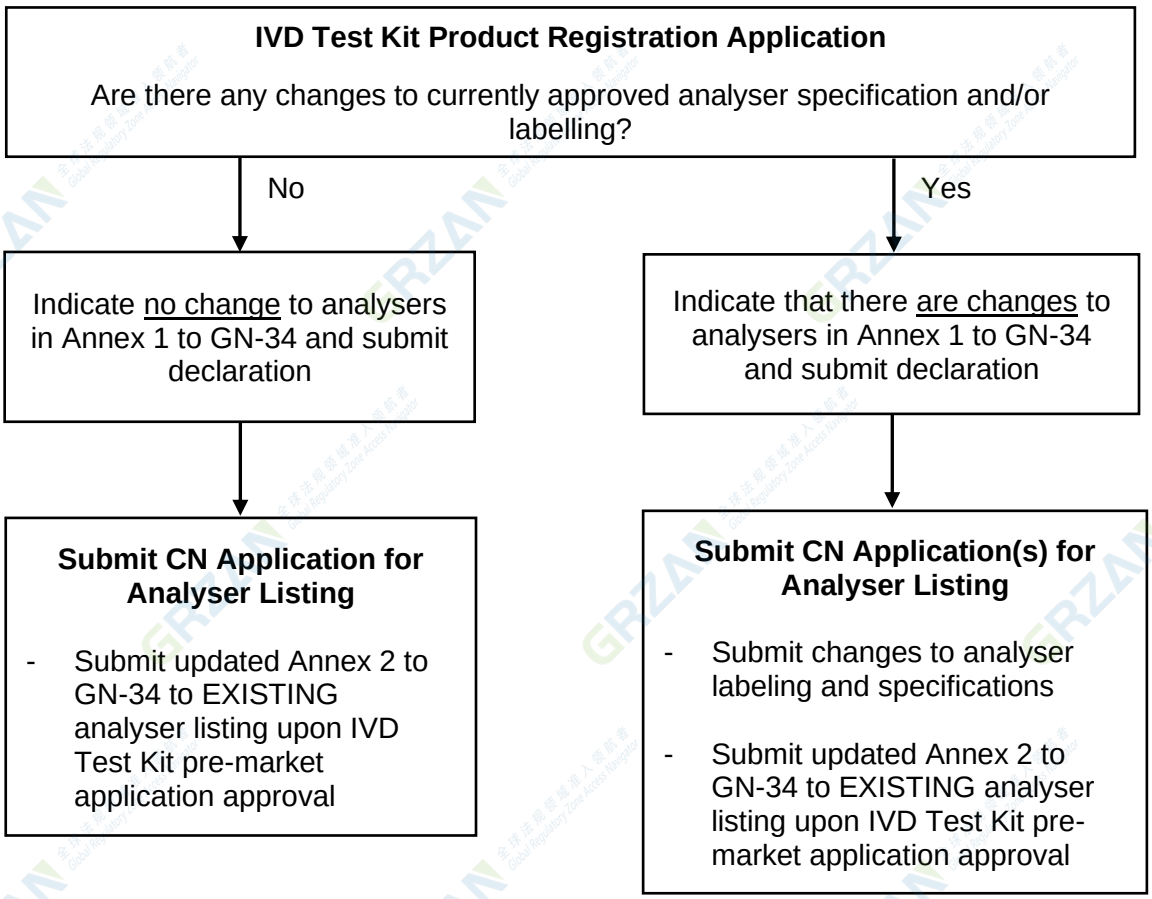
- R1.3 ► Registrants are to submit the declaration for registered IVD analysers in SPLIT IVD analyser device listings (Refer to Annex 1 for declaration template) ◄

- Registrants are to submit a Change Notification application for the affected analyser device listing, to update the list of registered reagents that are compatible and intended for use with the listed analyser (R1.3 ► Refer to Section 5.3 of this guidance for more information◄)
- Registrants are to submit the proposed changes made to the registered analyser in the IVD analyser listing (R1.3 ► Refer to Section 5 of this guidance for more information◄)

Refer to Flowchart 4 for an overview on the workflow.

Flowchart 4: Product Registration Workflow for IVD Test Kits which have Compatible Closed-System IVD Analysers Currently Listed on SMDR in their own Analyser Device Listing(s)

R1.3 ►



5. CHANGE NOTIFICATION APPLICATIONS

Changes described in this section are intended to complement change categories in GN-21 Guidance on Change Notification for Registered Medical Devices.

R2 ► -- ◄

5.1. Addition of Analyser to a Device Listing

R2 ► -- ◄

Change Notification submission, to add IVD closed-system analyser(s) to an existing listing, can proceed under change type 6Aiii in situations where

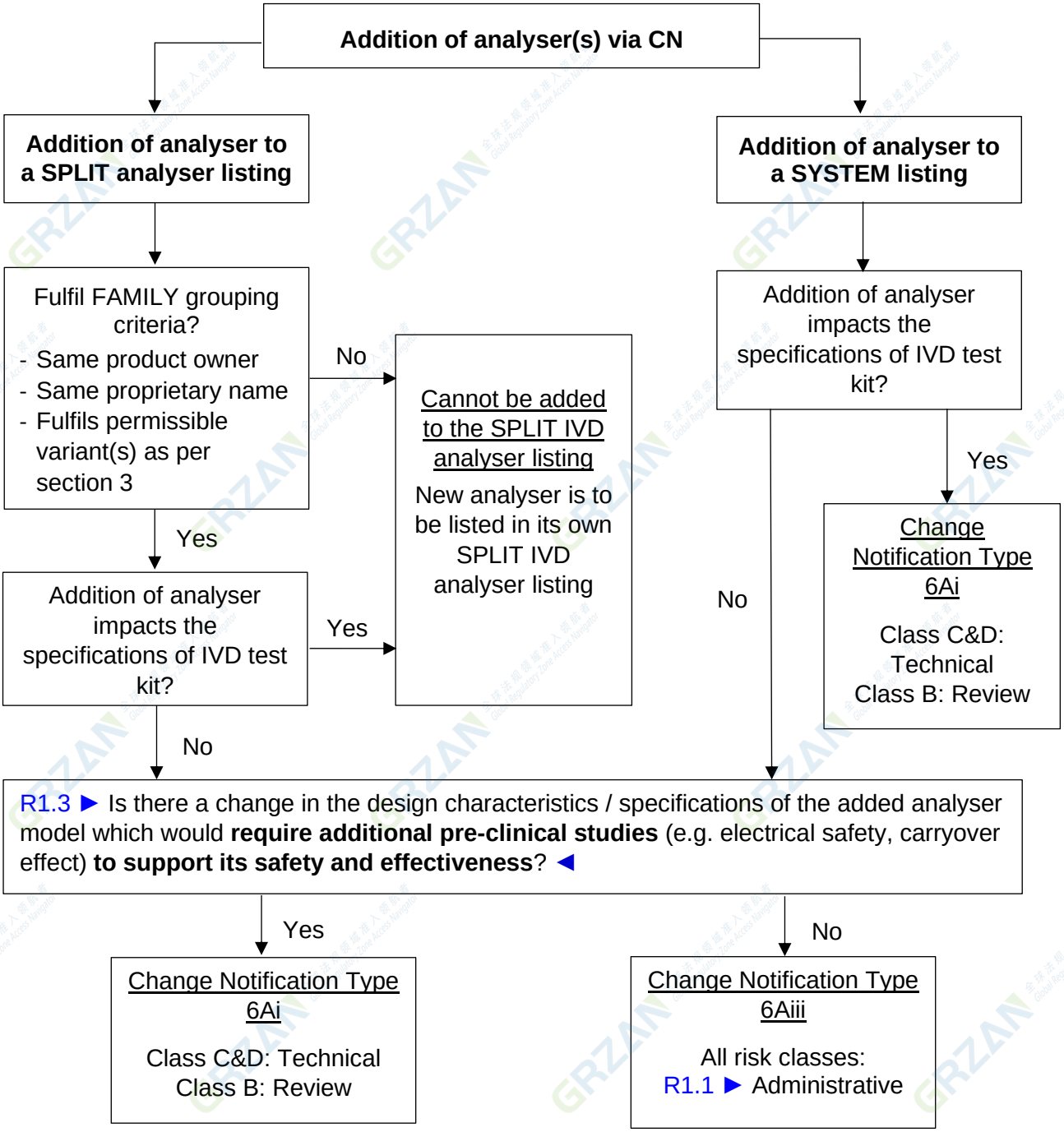
- addition of new IVD analyser(s) have no impact to the specifications of compatible IVD reagent(s) and
- no additional pre-clinical studies (e.g. electrical safety, carryover effect) are required to support the new IVD analyser's safety and effectiveness

For all other cases, change type 6Ai will be applicable.

New analysers to be added to a SPLIT IVD analyser listing must also fulfil the FAMILY grouping criteria highlighted in Section 3 of this guidance to qualify for addition via Change Notification route.

Refer to Flowchart 5 for an illustration of the applicable workflow.

Flowchart 5: R1.3 ► Workflow for Applicable Change Notification Types for the Addition of Analyser to **SPLIT** IVD Analyser or IVD **SYSTEM** Listing ◄



5.2. Changes to IVD Analysers

R2 ► Refer to GN-21 Guidance on Change Notification for Registered Medical Devices. ◄

Applicants are advised to review all applicable flowcharts and identify all relevant changes impacting the medical device, before submitting Change Notification accordingly for all affected SMDR listing(s).

Changes to the software of the IVD analyser may also impact the performance characteristics and/or specifications of the separately listed, compatible IVD reagent. Under such circumstances, Change Notification may need to be submitted for the IVD reagent listing.

5.3. Changes to the List of Compatible IVD Reagent Kits for SPLIT IVD Analyser Device Listings

For closed-system IVD analysers listed in their own device listing (SPLIT IVD analyser listing), Change Notification to update the list of compatible IVD reagents will be required whenever a new IVD reagent kit compatible to the listed IVD analyser is registered.

R2 ► Change Notification should be submitted for the closed-system IVD analyser listing under category 'Other Notification Changes (Verified by HSA prior to submission)'. The following supporting documents will be required:

- A copy of the confirmation email from HSA for the change notification application. This document is to be uploaded into this folder in SHARE: "Supporting Documents > Email Correspondence with HSA"
- GN-34 Annex 2 List of compatible reagents with analysers in SPLIT IVD analyser device listings
- GN-21 Annex 2 Summary Table of Change Notification ◄

6. SPLIT ANALYSER LISTING OPTION FOR REGISTERED IVD SYSTEMS ON THE SMDR

Note: *This section is only applicable to IVD systems registered on the SMDR before the **SPLIT** listing options for analysers and reagents were implemented (WEF 01/12/2017).*

Registrants that wish to opt for the **SPLIT** listing option for existing registered IVD systems, comprising of IVD analysers and their compatible reagents listed together on the SMDR, can do so via Change Notification.

R2 ► When the proposed changes consist **solely** of filing for the SPLIT listing option, Registrants are to email HSA to obtain confirmation of eligibility for split listing. After which, Registrants may submit Change Notification under the Change Notification type of 'Other Notification Changes (Verified by HSA prior to submission)'. Where the changes are identical (i.e. the same analyser / analysers to be removed from the IVD system listings), companies can group the affected device listings of the same risk class together in one application. ◄

In the Change Notification application filed for the SPLIT listing option, registrants will need to update the model information of all affected device listings to remove the analysers and proceed to create new device listings for the analysers. Only analysers that meet the 'FAMILY' grouping criteria in GN-12-1 Guidance on Grouping of Medical Devices and contains permissible variants in Section 3 of this guidance will be permitted to be listed under one device listing. Analyser accessories such as consumables and bulk solutions may be listed together with their compatible analysers in the analyser device listings.

Registrants are to provide the following for Change Notification submission:

- Annex 2 to GN-34
- Confirmation of the software version and device labelling (inclusive of user manual) intended for import and supply
- Master copy of Annex 2 List of Configurations specifying the models to be removed from the affected device listings and which are to be added to the new **SPLIT** analyser device listings created.
- R2 ► A copy of the confirmation email from HSA on the eligibility to split list the analyzer(s). This document is to be uploaded into this folder in SHARE: “Supporting Documents > Email Correspondence with HSA” ◄

Note: For the other applicable Change Notification documents, please refer to GN-21 Guidance on Change Notification for Registered Medical Devices for more information.

ANNEX 1

Declaration for Registered IVD Analysers in SPLIT IVD Analyser Device Listing(s) Template

[To be printed on Company Letterhead of Applicant]

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

[Name of Company], the Applicant for registration of the medical device(s) stated below, hereby declare that:

The compatible analyser(s) for the medical device(s) in this application is as per indicated in Table 1: List of Compatible Analyser(s).

Table 1: List of Compatible Analyser(s)

Name of analyser (as per device labelling)	Software version	Device Registration Number

R1.3 ►
☐ There are no changes to the currently approved compatible analyser(s) specifications, including the analyser software versions, labels and/or user manuals.

☐ There are changes to the currently approved compatible analyser(s) specifications, including the analyser software versions, labels and/or user manuals. Change notification application(s) shall be submitted for these changes under the respective affected analyser device listing(s). ◄

Upon approval of this pre-market application, a change notification application shall be submitted for the affected analyser device listing(s) to update the list of registered reagents compatible with the analyser.

This declaration shall apply to the following medical device(s):

[List containing product names of IVD reagents/ assays]

I, the Applicant, am aware that making a declaration which I know to be false is an offence under Section 30(10) of the Health Products Act (Cap. 122D) and may result in the cancellation of registration of the above medical devices under Section 37(1) of the Act.

Yours Sincerely,

[Signature]

[Full Name and Title of Senior Company Official]

[Name and address of company]

ANNEX 2

List of Compatible Reagents with Analysers in SPLIT IVD Analyser Device Listings Template

Compilation of Compatible Reagents with <Name of Analyser>

Analyser identifier: <indicate identifier of analyser>

Software version(s): <indicate currently-approved software version i.e. X.XX.XX>

Date of addition (DD/MM/YYYY)	Date of removal (DD/MM/YY) *<if applicable>*	Name of Reagents (as per device labelling)	Singapore Medical Device Registration (SMDR) number
Example:			
07/05/2017		*XYZ reagent*	*DE1234567*

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

11 Biopolis Way, #11-03 Helios
Singapore 138667
www.hsa.gov.sg

HSA
Health Sciences Authority