Change Notification applications arising from the EU MDR/IVDR related changes to registered medical devices

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Medical Devices Cluster
Health Products Regulation Group

NOTE: This document is to be read in conjunction with the current GN-21: Guidance on Change Notification for Registered Medical Devices

Revision History

Guidance Version (Effective Date) [3 latest revisions]	Revision
GL-09: Revision 1 (06 October 2020)	R1
R2 ►GL-09: Revision 2 (20 November 2023)	R2

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

Introduction

European Union (EU) is one of HSA's reference regulatory agencies commonly referenced in the abridged evaluation route for medical device registration. With EU's recent regulatory framework transition to the Medical Devices Regulation (MDR) and IVD Regulation (IVDR), the related changes will impact existing registered medical devices, especially IFU and labels. This document serves to provide clarity on HSA's position on change notification applications related to EU MDR and IVDR updates. This document will be effective until end of 2025.

For changes that do not fall within the covered scope and criteria in the subsections of this document, approach as prescribed in GN-21: *Guidance on Change Notification for Registered Medical Devices* will apply.

Revised Approach specific to changes arising from the EU MDR/IVDR

- Changes to label and IFU with no new information related to safety and performance (GMD and IVD) =>
  CN submission not required

- Changes to label and IFU related to material "-Free" claims (GMD) =>
  Change type 5E, Notification Change

- R2 ► Changes to IFU related to clarification of existing content and addition of safety information (GMD and IVD) => ***
  Change type 5E, Notification Change

- R2 ► Changes to IFU (IVD) related to clarification of performance data => ***
  Change type 5E, Notification Change

***Note: For changes to IFU (IVD) which:
(i) impacts indication of use, AND
(ii) is not covered under previously-submitted pre-clinical/clinical validation, please refer to GN-21 for the appropriate CN category and documents required.

Changes that do not require CN Submission

Changes to label and IFU with no new information related to safety and performance (GMD and IVD)	
Scope	• Addition of symbols to harmonise information between label and IFU • Addition of warnings and precautions related to safe disposal of the device • Addition of Carcinogenic, Mutagenic, Toxic to Reproduction (CMR)/ Endocrine Disrupting (ED) safety information • Addition of symbols related to intended user • Addition of hyperlink to EUDAMED's Summary of Safety and Performance • Addition of statement to report serious safety incident to EU manufacturer and Member State competent authority • Change in design of existing symbol
Criteria	• Changes due to EU MDR/IVDR updates • No change to material / material composition • No change to method of use / existing users • No addition of pack size • No change to sterile packaging • No new safety and performance data • No additional pre-clinical/clinical validation is required to support safety and effectiveness

Changes that do not require CN Submission

Changes to label and IFU with no new information related to safety and performance (GMD and IVD)	

Examples	• Date of manufacture
	• Symbols:
	  • MD
	  • Refer to IFU
	  • Repackaging
	  • Latex
	  • DEHP
	  • Single-use device
	  • Near patient testing
	  • Self-testing
	  • Contains hazardous substances
	• EUH 208: May produce an allergic reaction
	• Warning related to disposing infectious or microbial waste
	• Addition of statement “Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established”

CN Submission	Not required

Notification Change

Changes to label and IFU related to material “-Free” claims (GMD)	
Scope	• Addition of symbols and information on label and IFU related to material “-Free” claims
Criteria	• Changes due to EU MDR updates • No change to material • No change to method of use • No additional pre-clinical/clinical validation is required to support safety and effectiveness
Examples	• Addition of DEHP-Free symbol • Addition of Latex-Free symbol
CN Submission	Notification – 5E Other labelling changes
Documentary Requirements in addition to GN-21	• Annex 1: Medical Device MDR/IVDR Changes Declaration from Registrant • Evidence to support addition of symbol across all affected devices (e.g. list of materials, test report, safety data sheet)

Notification Change

R2 ►Changes to IFU related to clarification of existing content and addition of safety information (GMD and IVD) *** ◄	
Scope	• Minor update of intended use with no change to approved scope • Addition of symbols and rephrase of existing information for clarity • Addition of adverse events and side effects
Criteria	• Changes due to EU MDR/IVDR updates • No change to existing scope of approved intended use/indication • No change to method of use • No new safety and performance data • No change to device design, specifications or performance • No additional pre-clinical/clinical validation is required to support safety and effectiveness
Examples	• Rephrase intended use for clarity, based on R2 ►previously-submitted ◄ clinical studies • Additional description of technology used in device • Addition of adverse reactions
CN Submission	Notification – 5E Other labelling changes
Documentary Requirements in addition to GN-21	• Annex 1: Medical Device MDR/IVDR Changes Declaration from Registrant • Other relevant documents supporting proposed changes (e.g. risk analysis)

***Note: For changes to IFU (IVD) which:
(i) impacts indication of use, AND
(ii) is not covered under previously-submitted pre-clinical/clinical validation, please refer to GN-21 for the appropriate CN category and documents required.
For changes to IFU (IVD) that changes the intended use, please note that CN is **not applicable** and that a new pre-market application should be submitted. For risk classification based on the new intended use, please refer to GN-14 Risk classification of in-vitro diagnostic devices.

Notification Change

R2 ►**Changes to IFU related to clarification of performance data (IVD) ***** ◄	
Scope	• Addition or clarification of performance data, based on previously submitted pre-clinical or clinical studies
Criteria	• Changes due to EU IVDR updates • No change to method of use • No change to device design, specifications or performance • No additional pre-clinical/clinical validation is required to support safety and effectiveness
Examples	• Addition of acceptance criteria value, based on previously submitted pre-clinical studies
CN Submission	Notification – 5E Other labelling changes
Documentary Requirements in addition to GN-21	• Annex 1: Medical Device MDR/IVDR Changes Declaration from Registrant • Evidence of traceability to R2 ►previously-submitted ◄ pre-clinical/clinical validation (i.e. MEDICS job reference number and pre-clinical document file name, or re-submission of old performance study report)

***Note: For changes to IFU (IVD) which:
(i) impacts indication of use AND
(ii) is not covered under previously-submitted pre-clinical/clinical validation, please refer to GN-21 for the appropriate CN category and documents required.
For changes to IFU (IVD) that changes the intended use, please note that CN is **not applicable** and that a new pre-market application should be submitted.
For risk classification based on the new intended use, please refer to GN-14 Risk classification of in-vitro diagnostic devices.

Submission of changes affecting multiple registered medical devices

HSA will consider the **same symbol change and/or same IFU changes** across different dossiers and product identifiers if:

- changes are in context of EU MDR/IVDR updates, and meet the criteria for submission as described in the previous slides
- device listings are of the same risk class
- change involves identical symbols and or identical statement/paragraph

There will be no cap to the number of listings in one CN application as long as the changes are identical*.

Companies are to indicate on Annex 2 to GN-21 Table of Change that the changes are related to EU MDR/IVDR.

**Exact same symbol and/or statement across device listings*

Submission of changes affecting multiple registered medical devices

If there is a main device listing that has all the changes followed by device listings which have a subset of the changes, company is to provide representative labels/IFU for each subset in one CN application. Companies should also provide a table, which matches each set of submitted representative label(s) with the corresponding individual device model(s). See examples.

Company may provide a comparison table between current and proposed IFUs. Table should include but not limited to: IFU page number, specific IFU section(s) and details of changes made to the content (e.g. describe changes made to wording, images and diagrams). This is only applicable to IFUs.

Submission of changes affecting multiple registered medical devices

- Notification changes due to EU MDR/IVDR updates can be bundled together and notified to HSA in one change notification application, subject to submission grouping guidelines as specified under GN-21: *Guidance on Change Notification for Registered Medical Devices* and this *document*. Such change shall be submitted within a maximum of 6 months, from the point of first implementation, globally.

- For all remaining changes that do not fall within the previously covered scope and conditions, approach as described in GN-21: *Guidance on Change Notification for Registered Medical Devices* will apply.

Example 1

GMD Device listings (Same risk class)	Device Listing 1 (Device model A) Device Listing 2 (Device model B) Device Listing 3 (All device models)	Device Listing 4 (All device models) Device Listing 5 (Device models C and D)	Device Listing 6 (Device model E) Device Listing 7 (All device models)
Change A **Addition of Latex Free Symbol**	✓		✓
Change B **Addition of DEHP Free Symbol**	✓	✓	
Representative redlined and clean label	1 representative set	1 representative set	1 representative set

CN Submission	Submit 1 CN application Notification – 5E Other labelling changes
Documentary Requirements in addition to GN-21	• Annex 1: Medical Device MDR/IVDR Changes Declaration from Registrant • Evidence to support addition of symbol across all affected devices (e.g. list of materials, test report, safety data sheet)

Example 2

IVD Device listings (Same risk class)	Device Listing 1 (All device models)	Device Listing 2 (Device models A and B)	Device Listing 3 (All device models)
Change A **Rephrase intended use for clarity, based on earlier submitted clinical studies**	✓		✓
Change B **Clarification of acceptance criteria under IFU, Precision data section**	✓	✓	
Redlined and clean copy of IFU	✓	✓	✓

CN Submission	Submit 3 individual CN applications Notification – 5E Other labelling changes
Documentary Requirements in addition to GN-21	• Annex 1: Medical Device MDR/IVDR Changes Declaration from Registrant • Evidence of traceability to R2 ► previously-submitted ◄ pre-clinical/clinical validation (i.e. MEDICS job reference number and pre-clinical document file name, or re-submission of old performance study report)

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