



# Preparation of Medical Device Registration Dossier

## Updates to guidance documents

**Medical Devices Cluster**

23 November 2018

# Scope

1

GN-17 & GN-18 Guidance Documents

2

Technical Reference Documents

3

Product Registration Submission Guides



# **(1) GN-17 & GN-18 Guidance Documents**

# Current Guidance Documents

Industry  
feedback

Lack of  
clarity

Complicated

Too  
technical

# Guidance Documents – Expectations

Revamped GN-17 and GN-18 guidance documents:



Simple



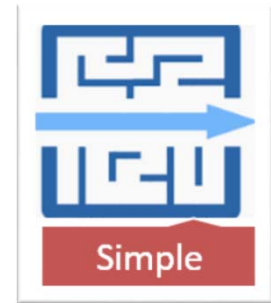
Salient



Succinct



# GN-17 & GN-18 Guidance Documents - Changes



## 4.4.1. Samples of Labels on the Device and its Packaging

ASEAN Common Submission Dossier Template, Document No.: N0013

### 4.4.1 Samples of Labels on the Device and its Packaging

This is the printed, written or graphic product information provided on or attached to one or more levels of packaging, including the outer packaging or the outside container wrapper. Any pack labelling, which is not provided on the outer packaging must be easily legible through this outer packaging.

If it is physically impossible to include samples of labels (e.g. large warning labels affixed onto an X-ray machine), alternative submission methods (e.g. photographs or technical drawings), to the extent appropriate, will suffice to meet the requirements of this section.

#### Guidance:

The labels on the medical device and its packaging are to be provided for the primary and secondary levels of packaging and shall be provided in the original colour. The labels can be provided in the form of artwork. Labels provided must be in English. Labels must be provided for all the components of a medical device system, members of a medical device family and accessories submitted for registration. Alternatively, a representative label may be submitted for variants, provided the variable fields on the artwork are annotated, and the range of values for the variable fields are indicated.

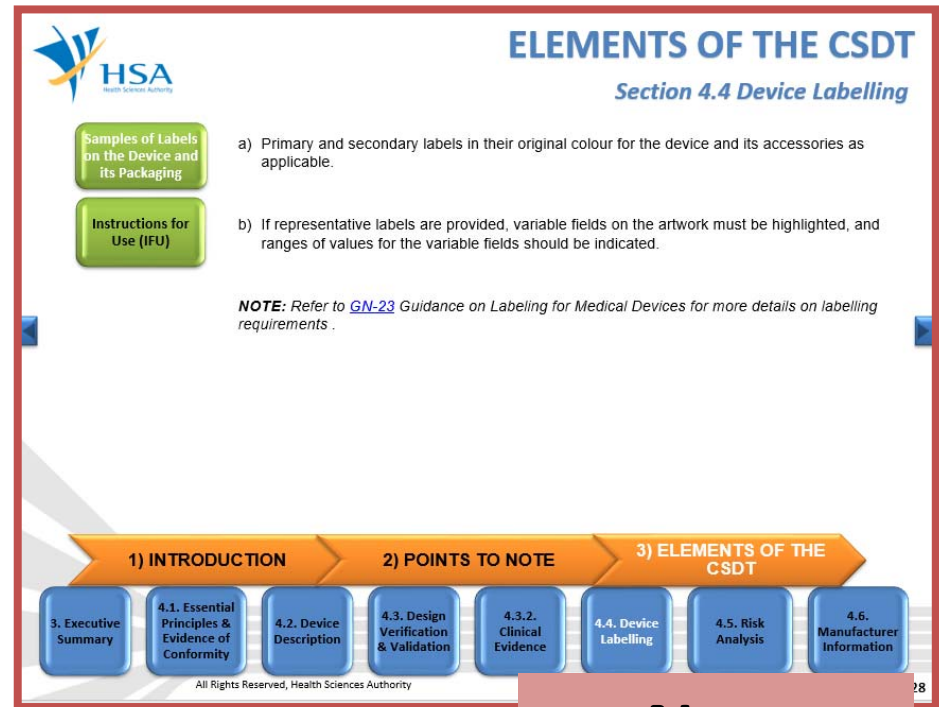
## 4.4.2. Instructions for Use

ASEAN Common Submission Dossier Template, Document No.: N0013

### 4.4.2 Instructions for Use

The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions to use a device safely and for its intended purpose.

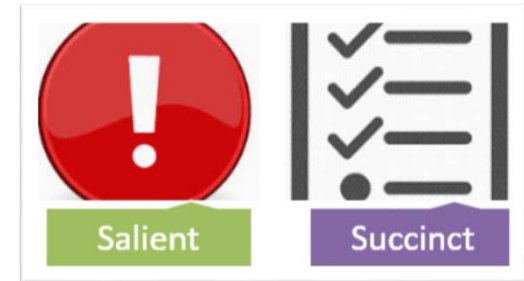
**Current**



Simple layout      Reader friendly

**New**

# GN-17 & GN-18 Guidance Documents - Changes



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ASEAN Common Submission Dossier Template, Document No.: N0013

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The instructions for use is commonly referred to as the physician's manual, user manual, operator's manual, prescriber's manual or reference manual. It contains directions under which the physician or end-user can use a device safely and for its intended purpose. This should include information on indications, contraindications, warnings, precautions, potential adverse effects, alternative therapy and the conditions that should be managed during normal use to maintain the safety and effectiveness of the medical device.

There is no specific guidance for this section of the

Samples of Labels on the Device and its Packaging

Instructions for Use (IFU)

- a) Primary and secondary labels in their original colour for the device and its accessories as applicable.
- b) If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated.

**NOTE:** Refer to [GN-23](#) Guidance on Labeling for Medical Devices for more details on labelling requirements.

Samples of Labels on the Device and its Packaging

Instructions for Use (IFU)

- a) Copy of the IFU to be supplied in Singapore for the device and its accessories as applicable.
- b) Indicate format of the IFU to be supplied with every medical device e.g. paper or electronic.

**NOTE:** Refer to [GN-23](#) Guidance on Labeling for Medical Devices for more details on labelling requirements.

**Current**

**New**

Greater clarity

Bite-sized information



# GN-17 & GN-18 Guidance Documents



Interactive

Sub-sections within each CSDT section

## ELEMENTS OF THE CSDT

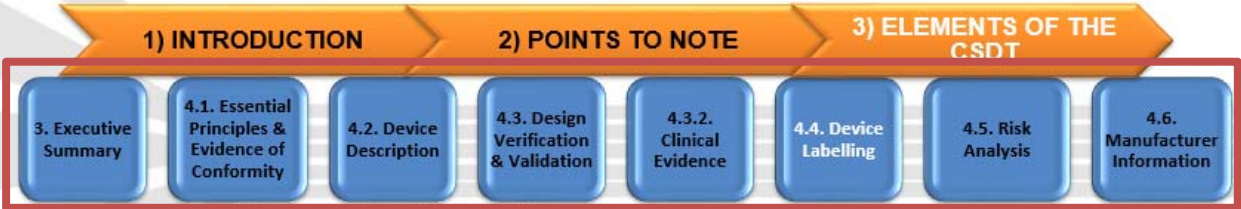
Section 4.4 Device Labelling

- Samples of Labels on the Device and its Packaging
- Instructions for Use (IFU)

- a) Primary and secondary labels in their original colour for the device and its accessories as applicable.
- b) If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated.

**NOTE:** Refer to [GN-23](#) Guidance on Labeling for Medical Devices for more details on labelling requirements.

Link to reference document



Sections of the CSDT

## GN-17 & GN-18 Guidance Documents

Requirements in GN-17 & GN-18 updated to include:

- Standard input request queries
- Feedback from focus group session in August 2017

### GN-17 & GN-18:



#### Instructions for use

“To indicate format of the IFU to be supplied with every medical device e.g. paper or electronic.

***NOTE:** Refer to GN-23 *Guidance on Labeling for Medical Devices* for more details on labelling requirements.”*



#### Important safety & performance related information

“For FSCAs that are ‘open’, to provide a description of any analysis and/or corrective and preventive actions (CAPA) undertaken by the product owner.”

## GN-17 & GN-18:



### Commercial marketing history

- To focus commercial marketing history on HSA's reference regulatory agency jurisdictions
- Clarification on "first introduction for commercial distribution"

*"List of countries from HSA's reference regulatory agency jurisdictions where the medical device is marketed"*

*"Date (accurate to MMYYYY) and country where the device was first introduced for commercial distribution\*, globally.  
\*refers to supply for clinical purpose"*



### Stability studies

"If available, both real time and accelerated stability studies are to be submitted. If real time aging has not been performed, adequate justification must be provided."

*Where there are on-going real time studies, indicate estimated completion date for such studies.*

## GN-17 & GN-18:



### Cybersecurity

“Evidence to support the cybersecurity of connected medical devices e.g. wireless enabled, internet-connected and network-connected devices. For example but not limited to:

- Cybersecurity vulnerabilities and risks analysis
- Cybersecurity control measures
- On-going plans, processes or mechanisms for surveillance, timely detection”

## GN-17 & GN-18:



### Reference and comparison to similar and/or previous generations of the device

“Where safety and effectiveness data of similar or previous generation devices are used in the current submission, the following information is to be provided:

- A list of such devices and specific information on the registration status of these devices with HSA are to be included (e.g. Device registration number).
- A comparison, preferably in a table, of the design, specifications and intended use/indications for use between the subject device in the current submission and the comparator devices (similar and/or previous generation). To include labelled pictorial representation (diagrams, photos, drawings) where necessary.”

## GN-17:



### Materials

“Where there are specific concerns related to the material safety (e.g. impurities or residue levels), additional information on the quality and safety of such materials may be required (e.g. conformity to relevant material standards, Certificate of Analysis)”

## GN-18:



### Electrical Safety & Electromagnetic Compatibility

“Evidence supporting electrical safety and electromagnetic compatibility of the analyzer”

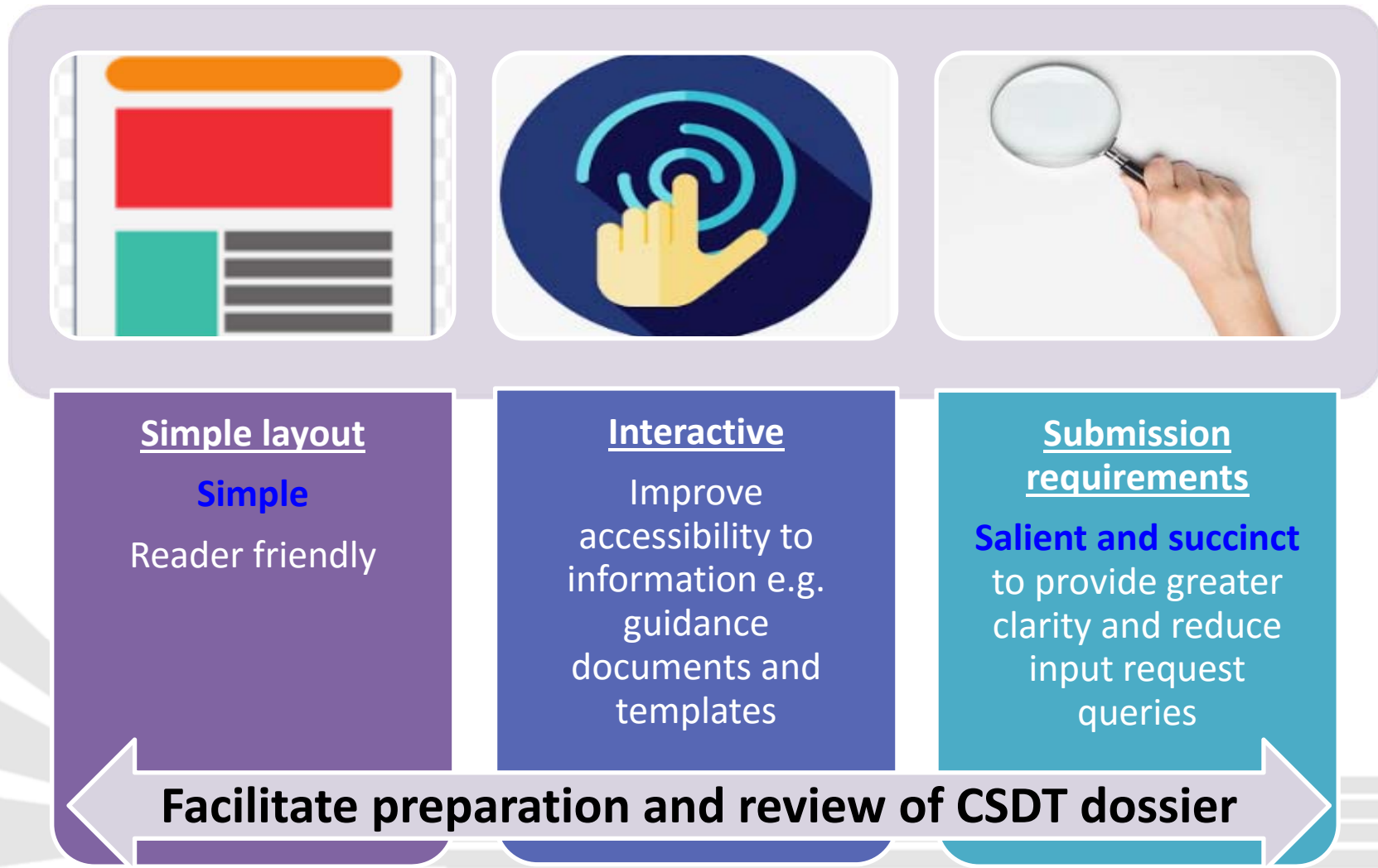


### Other Evidence

“For non-IVD medical device accessories to be registered with the IVD medical device, information on preclinical studies necessary to establish the safety and performance of these medical devices shall be provided e.g. biocompatibility and sterilisation validation studies”

# GN-17 & GN-18 Guidance Documents

## Key changes:



## (2) Technical Reference Documents



### Conversion of current GN-17 and GN-18 guidance documents into Technical Reference documents

- Technical information within these documents remain useful
- Allows a more in-depth understanding of the documentary requirements

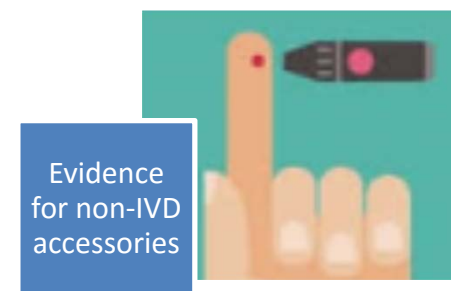
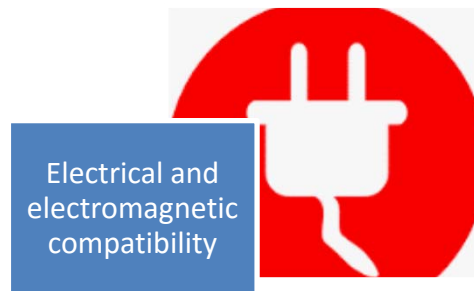
**TR-01:** Contents of a Product Registration Submission for **General Medical Devices** using the ASEAN CSDT



**TR-02:** Contents of a Product Registration Submission for **In Vitro Diagnostic Medical Devices** using the ASEAN CSDT

## (2) Technical Reference Documents

No changes made to contents of TR-01 and TR-02 except content updates as per revamped GN-17 and GN-18:





## **(3) Product Registration Submission Guides**

# Submitting an online application to register MDs



Submit online to HSA via the Medical Device Information and Communication System (MEDICS)

ALL documents to be submitted under '7. Dossier & Supporting Document(s)' section in MEDICS application form

MD0410 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application

APPLICATION FORM			
<a href="#">1. Applicant Info</a>	<a href="#">2. Device Info</a>	<a href="#">3. Priority Review Scheme</a>	<a href="#">Please refer to the Guidelines on the...</a>
<a href="#">4. Details of Reference Agency</a>	<a href="#">5. Device Details</a>	<a href="#">6. Evaluation Route</a>	
<a href="#">7. Dossier &amp; Supporting Document(s)</a>	<a href="#">8. Remarks</a>		

## Compiling the contents of the application

- Large % of our registered MDs are from the US and EU manufacturers
- The manufacturers may have a technical file prepared for their MDs according to the IMDRF ToC format
- Pre-market applications for registration of MDs in Singapore are submitted on the online MEDICS portal and may be compiled from:
  - the ASEAN CSDT dossier format; or
  - the IMDRF ToC format from the manufacturer
- A mapping of our MEDICS module to the corresponding sections in the two dossier formats would facilitate compiling and uploading of documents/reports in the submission stage

# IMDRF Table of Contents (ToC)



[Non-In Vitro Diagnostic Device](#) Market Authorization Table of Contents (nIVD MA ToC)

[In Vitro Diagnostic Medical Device](#) Market Authorization Table of Contents (IVD MA ToC)

## Authoring group

- Regulated Product Submissions - **Table of Contents (ToC) Working Group**

## Scope of Work

- The ToC document lists the various headings required when filing medical device submissions to regulatory authorities in various IMDRF jurisdictions
  - Covers both common IMDRF content and also regional content for all submission types
- Singapore CSDT requirements have been submitted and are being incorporated into the IMDRF ToC document to be published next year.

# MEDICS Submission - Challenges

ALL documents to be submitted under '7. Dossier & Supporting Document(s)' section in MEDICS application form

MD0410 - PRE-MARKET APPLICATION FOR MEDICAL DEVICE > New Application			
APPLICATION FORM			
<a href="#">1. Applicant Info</a>	<a href="#">2. Device Info</a>	<a href="#">3. Priority Review Scheme</a>	<a href="#">Please refer to the Guidelines on the...</a>
<a href="#">4. Details of Reference Agency</a>	<a href="#">5. Device Details</a>	<a href="#">6. Evaluation Route</a>	
<a href="#">7. Dossier &amp; Supporting Document(s)</a>	<a href="#">8. Remarks</a>		

Please attach the following document(s) by typing in the path or click on the browse button.

1.	All ABR	Letter of authorization *	Browse...
2.	All ABR	Annex 2 List of Configurations *	Browse...
3.	All ABR	Proof of reference agency's approval(s) *	Browse...
4.	All ABR	Executive Summary *	Browse...
5.	All ABR	Essential Principles Checklist and Declaration of conformity *	Browse...
6.	All ABR	Device description *	Browse...

7.	All ECR	Design verification and validation documents including : <ul style="list-style-type: none"> <li>• Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</li> <li>• Meteorological requirements</li> <li>• Sterilisation validation (if applicable)</li> <li>• Shelf-life studies and projected useful life</li> </ul>	Browse...
8.	All ECR	Proposed Device Labelling *	Browse...
9.	All ECR	Clinical evidence *	Browse...
10.	All ECR	Risk Analysis *	Browse...
11.	All ECR	Manufacturing Information (sites name and address) *	Browse...
12.	All ECR	Proof of QMS - Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169 *	Browse...
13.	All ECR	Manufacturing Process - Flow Chart *	Browse...
14.	All ECR	Other document, please specify	Browse...

# Mapping the MEDIC modules to Dossiers

**NEW**

E-Submission Guide for **General Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS



E-Submission Guide for **In Vitro Diagnostic Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS



- Specifies the appropriate modules in MEDICS for uploading of the corresponding sections of the CSDT or IMDRF ToC dossier
- Includes guidance on submitting responses to input request queries
  - To provide a written response to each input request query
  - To indicate the relevant file name(s) in the response if these are used to support the response

# Mapping the MEDIC modules to Dossiers



ASEAN  
CSDT

## SECTIONS

- Executive summary
- Essential Principles & Evidence of Conformity
- Device Description
- Design Verification & Validation
- Clinical Evidence
- Device Labelling
- Risk Analysis
- Manufacturer Information



IMDRF  
ToC

## SECTIONS

- Chapter 1 Regional Administrative
- Chapter 2 Submission Context
- Chapter 3 Non-Clinical Evidence
- Chapter 4 Clinical Evidence
- Chapter 5 Labelling and Promotional Material
- Chapter 6A Quality Management System Procedures
- Chapter 6B Quality Management System Device Specific Information

7.	All ECR	Design verification and validation documents including : <ul style="list-style-type: none"> <li>• Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies</li> <li>• Meteorological requirements</li> <li>• Sterilisation validation (if applicable)</li> <li>• Shelf-life studies and projected useful life</li> </ul>
8.	All ECR	Proposed Device Labelling *
9.	All ECR	Clinical evidence *
10.	All ECR	Risk Analysis *
11.	All ECR	Manufacturing Information (sites name and address) *
12.	All ECR	Proof of QMS - Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169 *
13.	All ECR	Manufacturing Process - Flow Chart *

## To facilitate review of the pre-market application

- Applicants shall ensure that the relevant section of the dossier and supporting documents are uploaded correctly under each MEDICS module
- Document file names should also be **meaningful** and provide some indication of their content.

# E-Submission Guides

MEDICS Application Form - Dossier & Supporting Document(s)		Reference technical documents		Class B			Class C & D				
		IMDRF nIVD ToC	CSDT TR-01	F	A	I	F	A	E	I	
1	<b>Letter of authorization</b>										
	<ul style="list-style-type: none"> <li>Letter of Authorisation of Registrant by the Product Owner for all the products to be registered, using the latest template as per GN-15 <a href="#">Annex 1</a> Letter of Authorisation template</li> </ul>	CH1.13 Letter of Authorization	NA	✓	✓	✓	✓	✓	✓	✓	✓
2	<b>Annex 2 List of Configurations</b>										
	<ul style="list-style-type: none"> <li>A copy of <a href="#">Annex 2</a> for GN17 and GN18 List of Configurations, including the complete list of configurations of medical devices subject to the submission. This is to be submitted in a Microsoft Excel file.</li> </ul>	CH1.05 Listing of Device(s)	4.2 Device Description	✓	✓	✓	✓	✓	✓	✓	✓
3	<b>Proof of reference agency's approval(s)</b>										
	<ul style="list-style-type: none"> <li>Copies of approval letter(s) from each reference agency. For CE marked devices, the EU declaration of conformity by the product owner must be submitted, in addition to the EC certificate issued by the notified bodies.</li> </ul>	CH1.07 Free Sale Certificate/ Certificate of Marketing authorization	3. Executive Summary		✓	✓		✓	✓	✓	✓

Modules as per the 'Dossier & Supporting Document(s)' section of the MEDICS application form

Brief description of the expected contents to be uploaded under each of the modules

Sections of the CSDT or ToC to be uploaded under the respective module in MEDICS.

Data requirements for the respective evaluation routes (as per GN-15)

# E-Submission Guides

Documents that do not fit into any of the modules in MEDICS shall be uploaded under “Other document, please specify” e.g. HSA-specific information, input request response document

16 Other document, please specify										
	<ul style="list-style-type: none"> <li>Information on previous regulatory decisions (e.g. withdrawals or rejections by HSA) for the devices</li> </ul> <p><i>NOTE: You may be required to provide the previous submission or registration information where necessary.</i></p>	CH1.09 Pre-Submission Correspondence and Previous Regulator Interactions	NA	if applicable	if applicable	if applicable	if applicable	if applicable	if applicable	if applicable
	<ul style="list-style-type: none"> <li>Information on any ongoing AE or FSCA reported to HSA for the subject device.</li> </ul>									
	<ul style="list-style-type: none"> <li>Justification for an unmet clinical need</li> </ul> <p><i>NOTE: Applicable for Priority Review Scheme Route 1</i></p>									

# Conclusion

As part of our on-going efforts to improve the contents of our online materials to better benefit our stakeholders:



Greater clarity



Concise



Simple



Convenient



Documents will be published for stakeholder consultation after the session

