



**Cortellis Regulatory Intelligence**

# **Medical Devices and IVDs Comparison Table**

**包装および表示に関する各国間の規制要件を一覧で比較し整理する**

**Comparison Table**は同一の規制要件において、世界各国で異なるポイントをクイックに比較参照する際に役立つテーブル表です。2026年2月時点で以下のTOPICにて提供されており、複数国での規制対応調査を円滑に進めたいお客様をサポートします。

- **規制当局・関連組織** - 医療機器および体外診断用医療機器（IVD）に関する各国規制当局の基本情報（規制当局・保健省の名称と公式サイト、指定機関〔Notified Bodies〕等の有無・権限）
- **法的定義および製品分類** - 各国の医療機器およびIVDの製品分類制度（クラス区分、分類基準、クラス判定に用いるガイドライン）、関連する主要法令・規制要件
- **市場参入** - IVDの包装・表示要件および適用される表示・包装規格と必須表示事項、医療機器の広告規制要件（当局への申請・届出・承認要否、具体的手続）、医療機器の包装・表示要件および表示・包装規格と必須表示事項
- **広告・表示** - IVDの包装・表示要件および適用される表示・包装規格、医療機器の広告規制要件（当局への申請・届出・承認要否、具体的手続）、医療機器の包装・表示要件および表示・包装規格（必須表示事項やトレーサビリティ要件含む）
- **品質マネジメント** - IVDおよび医療機器に関する各国のQMS要件（GMP適用有無、必要手続、査察要否）
- **市販後監視** - 医療機器およびIVDの有害事象報告要件(報告期限、報告方法、定期報告の形式・頻度、提出先、報告DB等)
- **輸出入** - 医療機器の輸出入手続（必要書類や申請手続）

Comparison Tablesは医療機器・体外診断薬関連規制18種類の比較表を用意し、随時アップデートして提供しています。

Global Comparison <span style="float: right;">My Regions </span>					
▼ Apply Filters					
Country/Region	Medical Device Post-Marketing Authorization Procedures including Device Changes	Medical Device Post-Marketing Renewal Procedures and Timelines	Medical Device Post-Marketing Authorization Authorities involved	Medical Device Post-Marketing Authorization Applicable Classes	Regulatory S
Algeria	<ul style="list-style-type: none"> <li>Registration Certification is not mandatory yet</li> <li>Techni </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Yes, 5 years renewal of registration certifi </li> </ul>	<ul style="list-style-type: none"> <li>National Laboratory for Quality Control of Pharmaceutical Products </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: All</li> <li>Re-registration/Listing: All</li> </ul>	Medical De Framework
Argentina	<ul style="list-style-type: none"> <li>Variation registration</li> <li>Technical evaluation during reg </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Yes, 5 years renewal of registration certifi </li> </ul>	<ul style="list-style-type: none"> <li>Technical Commissions of Medical Device National Administration for M </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Class I (sterile or with measurement functio </li> </ul>	Medical De Framework
Australia	<ul style="list-style-type: none"> <li>Reassessment of Conformity</li> <li>Re-registration notification </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: No, annual fee must be paid</li> <li>Re-regist </li> </ul>	<ul style="list-style-type: none"> <li>Australian Conformity Assessment Body Therapeutic Goods </li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Is, Im, Iia, Iib III</li> <li>Re-registration/L </li> </ul>	Medical De Framework
Austria	<ul style="list-style-type: none"> <li>Re-assessment of Conformity (CF</li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Yes, 5 years renewal of CF</li> </ul>	<ul style="list-style-type: none"> <li>Notified Body Gesundheit Österreich GmbH (GÖG)</li> </ul>	<ul style="list-style-type: none"> <li>Re-Certification: Is, Im, Ir Iia, Iib III</li> <li>Re-registrati </li> </ul>	Medical De Framework

ここでは包装および表示に関する各国間の規制要件比較の一覧を確認する方法を紹介します。まず以下の黄色で表示されたLabeling and Promotionのカテゴリに属するMedical Device Labeling Requirementsをクリックします。

The screenshot shows a navigation menu with the following structure:

- All ⓘ
- Comparison Tables ⓘ
- Intelligence Reports
- Regulatory Summaries
- Source Documents

Below the navigation menu, there are two tabs: **Browse** and **Quick Search**. A search icon is visible to the left of the search bar.

The main content area is titled "Medical Devices and IVDs" and is organized into several expandable sections:

- ▶ **Authorities and Organizations**
  - IVD Regulatory Agency Directory
  - Medical Device Regulatory Agency Directory
- ▶ **Legal Definitions and Product Classification**
  - IVD Classification Summary
  - IVD Laws and Regulations Summary
  - Medical Device Classification Summary
  - Medical Device Laws and Regulations Summary
- ▶ **Market Clearance**
  - IVD Marketing Application Procedures
  - IVD Post-Marketing Procedures
  - Medical Device Marketing Application Procedures
  - Medical Device Post-Marketing Procedures
- ▶ **Labeling and Promotion**
  - IVD Labeling Requirements
  - Medical Device Advertising Requirements
  - Medical Device Labeling Requirements**

このテーブルは、医療機器の包装および表示要件の概要を提供することを目的としています。（適用される表示および包装基準に関する情報を提供し、特定の国の要件については包装または表示への記載が義務付けられているか否かにかかわらず、本概要に詳細が記載されています。また関連する参照文書およびガイドラインへのリンクも含んでいます。）

## Labeling and Promotion

テーブルをエクセル出力することが可能です。（次頁参照）

テーブルの更新があった際にお知らせを受け取るためのアラートを設定可能です。

フィルターを使用し、比較対象国を限定することが可能です。

Country/Region	regulatory : Labeling of	Are there any language requirements applying to Medical Device Labeling?	Are Medical Device manufacturer/authorized representative name and contact details required?	Is there any submission/approval required for Medical Devices Labeling and Packaging?	Are there any identification and/or traceability procedures for Medical Devices or Labelers?	Is UDI (Unique Device Identification) mandatory for Medical Devices?	Are there any special requirements/exemptions for Labeling specific Medical Devices?	Regulatory Summary	What is the regulatory basis for Medical Device Packaging and Labeling?	Reference Document(s) for Labeling Requirements applying to Medical Devices
Algeria		English or Arabic or French	Yes	Yes, as part of the registration procedure.	Mandatory traceability requirements	No	Depending on the intended use and indications for use (i.e. ...)	Medical Devices Regulatory Framework	ANPP Announcement No. 35/MIPH/ANPP/DG/NOTE/25: Note to Pharmaceutical ...	Order No. 25 of 12-Oct-2025 Establishing the Technical Conditions for ...
Argentina		Spanish	Yes	As part of the registration procedure	Mandatory traceability system for specific products: Cardioverter, El ...	Only for Cardioverter, Electrical stimulators for hearing in the coch ...	Sales conditions and license number. Depending on the ...	Medical Devices Regulatory Framework	Regulation 64/2025: Incorporates the MERCOSUR ...	Disposition 2303/2014: Establishes Traceability Requirements for the Medical ...
Australia	able to of ...	English	Yes	As part of the registration procedure for devices requiring applicati ...	Mandatory traceability requirements. Permanently implantable ...	Yes, for:  Class Is (supplied sterile)   from 01-Jul-2028   Class Ila ...	Depending on the intended use and indications for use (i.e. ...)	Medical Devices Regulatory Framework	Therapeutic Goods Act 1989, consolidated version as of 21-Mar-2025Regulations: ...	IMDRF Consultation: Unique Device Identification System, 13-Aug-2018Guideline: ...
Austria	ider nces - ...	German	Yes	Labeling information will be assessed by the Notified Body (NB) for C ...	Mandatory traceability requirements	Assignment of UDI will be mandatory as of 26 May 2020. Application of ...	CE Mark (including NB number as applicable). Depending on the intende ...	Medical Devices Regulatory Framework	Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical ...	Medical Devices Act 2021 (Medizinproduktegesetz 2021 - MPG 2021) (Consolidated ...

Country/Region	Are there any Packaging and Labeling standards applying to Medical Devices?	Is there an existing regulatory basis for electronic Labeling of Medical Devices?	Are there any language requirements applying to Medical Device Labeling?	Are Medical Device manufacturer/authorized representative name and contact details required?
China	The NMPA issued regulations pertinent to medical device instructions for use and labeling. Regarding the detailed requirements for medical device instructions for use and labeling, please see the CFDA Order No. 6: Regulations for Labels and Instructions for Use (IFU) for Medical Devices, 30-Jul-2014 (IDRAC 200661) and Regulations on Supervision and Administration of Medical Devices (Revised Version), 06-Dec-2024 (IDRAC 399006).	No	Simplified Chinese	Yes. The name, residence, manufacturing address, contacts and production license number or filing number of medical device manufacturer are required. For contract manufacturing, name, address, manufacturing address, production license number or filing number of contracted manufacturer shall be also specified.
Indonesia	Yes, refer to ASEAN labelling standards.	No	Indonesian and English	Yes
India	Symbols recognised by the Bureau of Indian Standards or ISO Standards	CDSCO accepts electronic instructions to use as well as paper instructions.	English	

- 医療機器に適用される包装および表示の基準は？
- 医療機器の電子表示に関する既存の規制基盤は？
- 医療機器の表示に適用される言語要件は？
- 医療機器の製造業者/認定代理店の名称および連絡先情報は必要か？
- 医療機器の表示および包装に関する提出/承認は必要か？
- 医療機器または表示業者に対する識別および/またはトレーサビリティ手順は？
- 医療機器に対するUDI（固有機器識別）は義務付けられているか？
- 特定の医療機器の表示に関する特別な要件/免除は存在するか？
- 医療機器の包装および表示の規制根拠は？
- 表示要件に関する参照文書

## Change History

Date	Country/Region	New/Updated	Section
07-Jan-2026	Hong Kong	Updated	What is the regulatory basis of Medical Device Packaging and Labeling?
07-Jan-2026	Hong Kong	Updated	Reference Document(s) for Labeling Requirements applying to Medical Devices
07-Jan-2026	Hong Kong	Updated	Regulatory Summary
25-Nov-2025	Indonesia	Updated	Is UDI (Unique Device Identification) mandatory for Medical Devices?

Cover Sheet   Subject Fields   **Change History**

Change Historyのシートを選択することで、テーブルの更新履歴一覧を確認可能です。



# Think forward

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