10th February 2022

Compliance & Risks

Webinar
Product Safety of Medical Devices: Reviewing the Regulatory Landscape

Presented by
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Agenda

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1. Brief Overview
   - Compliance & Risks - What we do
   - C2P - Our market access solution

1. Global Regulatory Developments in Medical Devices
   - Developments in Medical Devices Framework Regulations
   - List of Rules on Classification of Medical Devices
   - Rules and Guidance on Certification and Registration of Medical Devices

1. HOT Questions in the world of Medical Device Compliance

1. Q&A

What we do

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MISSION STATEMENT

We help ensure global companies have the tools to build safe, sustainable, products in a world full of change

A Finger on the Pulse of Regulatory Change

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IN NUMBERS

Medical Devices

64%

Growth in regulations over the past 5 years

13,485

in force and proposed regulations across the sector

195

countries monitored

MEDICAL DEVICES

INDUSTRY FIGURES

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C2P

The key to unlocking market access

Design & build new products with full confidence you've met all compliance obligations. Continually monitor regulatory changes around the world & keep ahead of proposed changes before they happen. Keep all compliance evidence up to date & live linked back to their Regulations, Standards and Requirements.

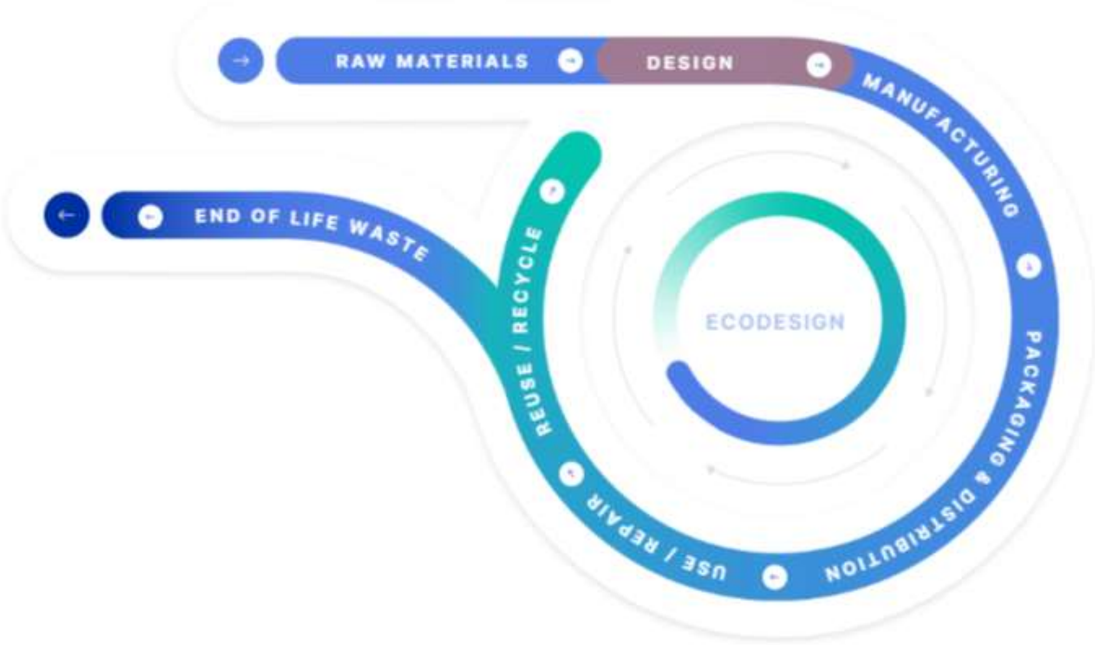
Simplify your product compliance process with C2P.

20+ Industry Sectors & 40+ Regulatory Topics

Content for the Full Product Lifecycle

We have the most comprehensive global coverage of Regulations & Standards covering the full product lifecycle from raw materials through to end of life.

- All topics updated on a daily basis
- Compliance news & alerts, requirements types, topics, materials & substances, products covered, key dates, deadlines, exceptions & exemptions
- Commentary from regional experts in the Americas, EMEA & Asia



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Global Regulatory Developments

1. Developments in Medical Device Framework Regulation
2. List of Rules on Classification of Medical Devices
3. Rules and Guidance on Certification and Registration of Medical Devices

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Developments in Medical Device Framework Regulation

Developments in Medical Devices Framework Regulation

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- EU Commission Published Rules for the Application of Regulation (EU) 2017/745 in Relation to European Database on Medical Devices
- EU Commission Proposed to Extend Transitional Periods for Certain Devices and Deferred Application of Requirements for in-house Devices
- EU Commission Amending Harmonised Standards for Certain Medical Devices
- EU Guidance Document on Application of MDR Requirements to Legacy Devices and to Device Placed on the Market prior to 26 May 2021
- UK Published Guidance Document on Regulating Medical Devices

Developments in Medical Devices Framework Regulation

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- US Proposed Guidance Document on Content of Premarket Submissions for Device Software Functions
- Brazil publication of Resolution RDC No. 546 on Approving Technical Regulation on Essential Safety and Performance Requirements for Medical Products
- South Korea issued Amendments to Medical Device Act with respect to Manufacturers and Importers' Obligations
- Vietnam Published the Decree No. 98 on Medical Devices Management,2021
- Saudi Arabia published Executive Regulations on Medical Devices and Supplies and a list of Guidance Documents

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List of Rules on Classification of Medical Devices

List of Rules on Classification of Medical Devices

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- Australia - List of Guidance Documents on Reclassification
- China - Catalogue of Class I Medical Device
- EU - Guidance on Classification of Medical Device
- India - List of Notices on Classification of Medical Devices including personal protective equipment and software
- Philippines - List of Class A Medical Devices
- Saudi Arabia - Guidance Document on Borderline Products Classification
- South Korea - Amendments to Classification of Medical Device and Class by Product on Adding New Medical Devices

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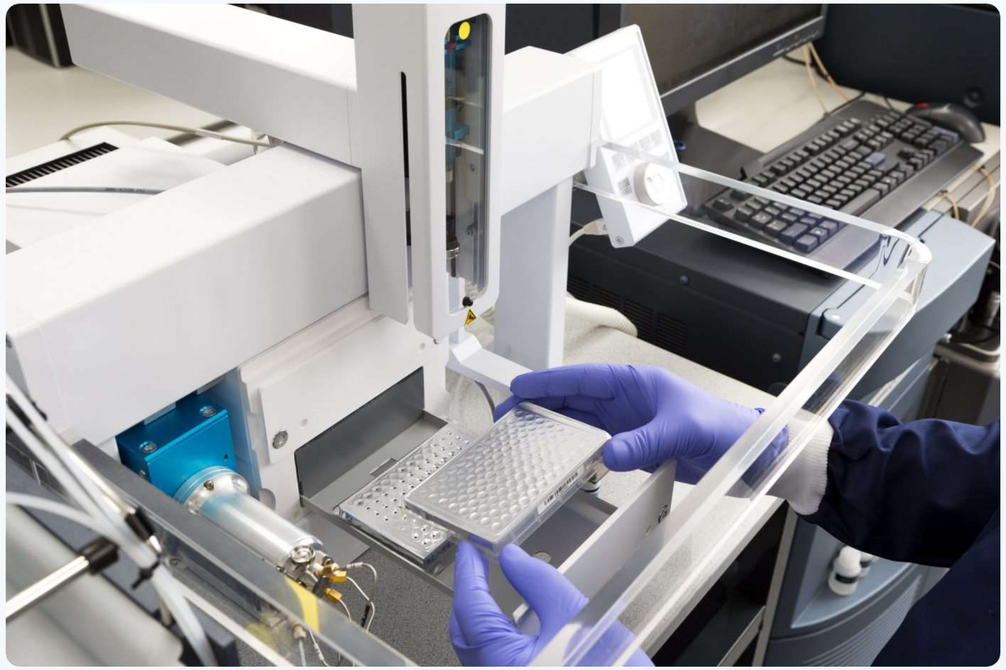
Rules and Guidance on Certification and Registration of Medical Devices



Rules and Guidance on Certification and Registration of Medical Devices

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- UK Updated Guidance Document on How to Register Medical Devices to Place on the Market
- China published Administrative Measures on Registration and Filing of Medical Device and the Emergency Approval Procedures for Medical Devices
- Singapore Issued a List of Guidance Documents on Registration of Medical Devices
- MERCOSUR Published Technical Regulation for Registration of in Vitro Medical Devices

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Hot Topics

What are the main changes regarding EU harmonised standards?

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- Harmonised standards published by the European Commission in support of the MDR and IVDR
- The European Committee for Standardization (CEN) & European Committee for Electrotechnical Standardization (Cenelec) revised existing harmonised standards and created new versions
- Implementing Decisions (EU) 2022/6 of 4 January 2022 and 2022/15 of 6 January 2022 regarding harmonised standards in support of Regulation (EU) 2017/745 (the "Medical Devices Regulation" - "MDR") and Regulation (EU) 2017/746 (the "In-vitro Diagnostic Medical Devices Regulation" - "IVDR")
- This reflects the latest technical and scientific developments, and to cover the requirements set out in the MDR and IVDR

More about IVDR and it’s timeline

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- The In Vitro Medical Devices Regulation (Regulation (EU) 2017/746) (IVDR) sets out the new regulatory framework for in vitro diagnostic (IVD) medical devices
- The European Commission proposed a progressive roll-out of the IVDR
- The IVDR will fully apply from 26 May 2022 for CE-marked devices/new devices which do not need involvement of notified bodies under the IVDR
- The European Commission proposed additional transition periods for certain devices

What is the current status of EUDAMED?

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Eudamed is the IT system developed by the European Commission

- Actors registration
- UDI/Devices registration
- Notified Bodies and Certificates
- Clinical Investigations and performance studies
- Vigilance and post-market surveillance
- Market Surveillance

The Commission Implementing Regulations came into force on 19 December 2021, and set out the rules for how Eudamed will operate, including accessing the database, collecting personal data and the procedure in case of malfunctions.

What about Great Britain?

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- The Medicines and Healthcare products Regulatory Agency (MHRA) published updated guidance on medical device regulation in the UK on 1 January 2022 - Updated to reflect changes to medical device regulatory requirements
- Registration with MHRA before they are placed on the Great Britain market
- CE marking will continue to be recognised in Great Britain until 30 June 2023
- Certificates issued by EU-recognised Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
- The EU no longer recognises UK Notified Bodies

What’s the impact of Vietnam’s new Medical Device Law?

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- On 1 Jan 2022, Decree No. 98 on management of medical devices came into force
- It replaced Decree No. 36/2016/ND-CP, Decree No. 169/2018/ND-CP and Decree No. 03/2020/ND-CP
- The Decree sets out new regulations on registration numbers of medical devices, the approval process for the registration of Class C and D medical devices, new regulations on import licenses, product classification, price management measures, advertisement, clinical trials, and post-market management
- The Common Submission Dossier Template (CSDT) application is mandatory from 1 January 2022
- Requirement to publish advertising content for medical devices will take effect from 1 July 2022

eIFUs - New Requirements

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- On 4 January 2022, the European Commission's new Implementing Regulation (EU) 2021/2226 for the use of electronic instructions for use (eIFUs) for medical devices came into force
- The Implementing Regulation applies to devices placed on the market under the Medical Devices Regulation (MDR) and repeals and replaces Commission Regulation (EU) 207/2012, which has allowed the use of eIFUs since 2013
- Expands the use of eIFUs to a larger group of medical devices
- Risk assessment must take into account eIFU’s compatibility with different devices that could be used to display the instructions
- GDPR-compliance

Questions?

FIND OUT MORE

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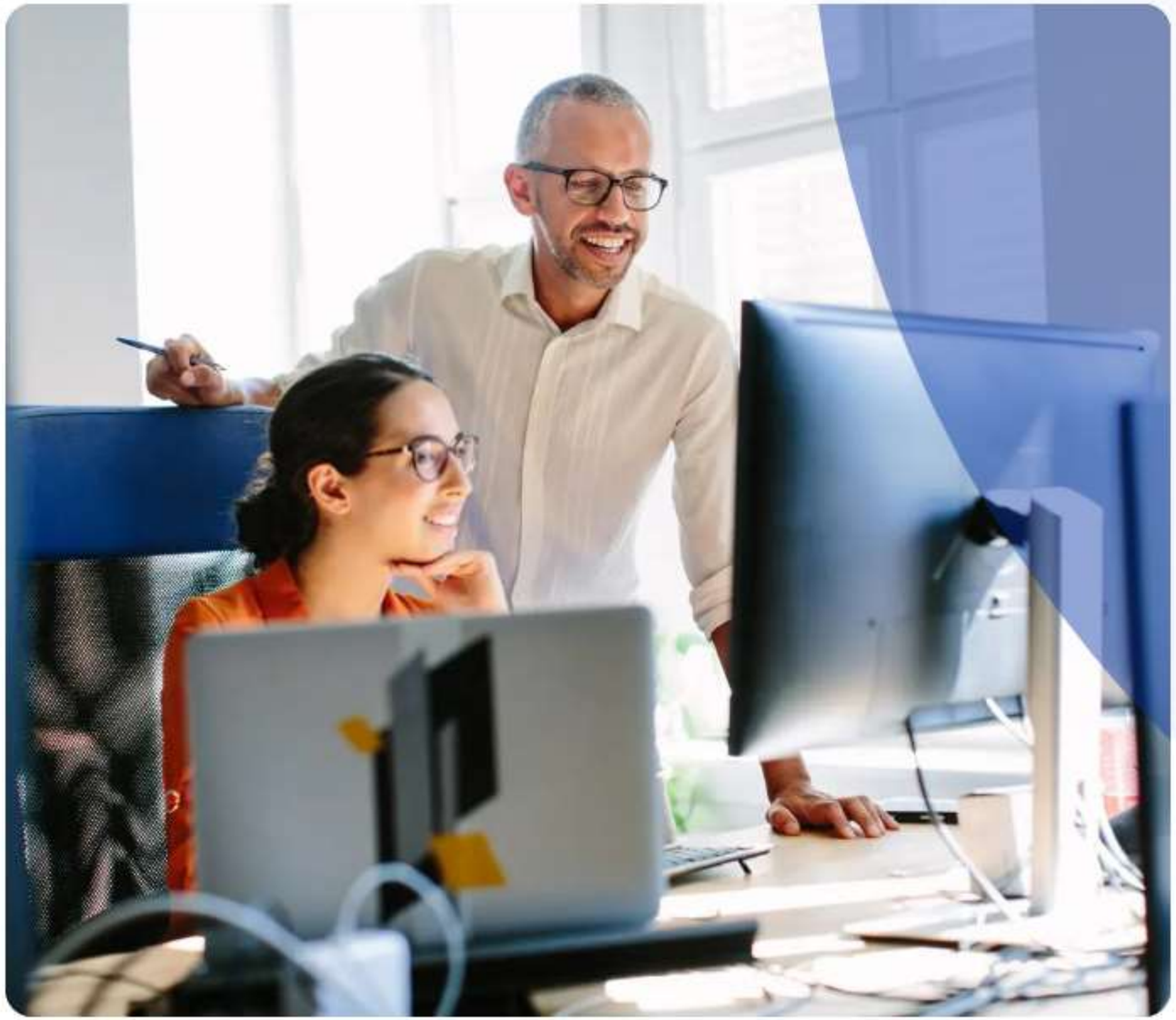

OUR TECHNOLOGY

C2P – Your complete market access & product compliance solution.

ASK OUR EXPERTS

BOOK A DEMO

Thank You

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