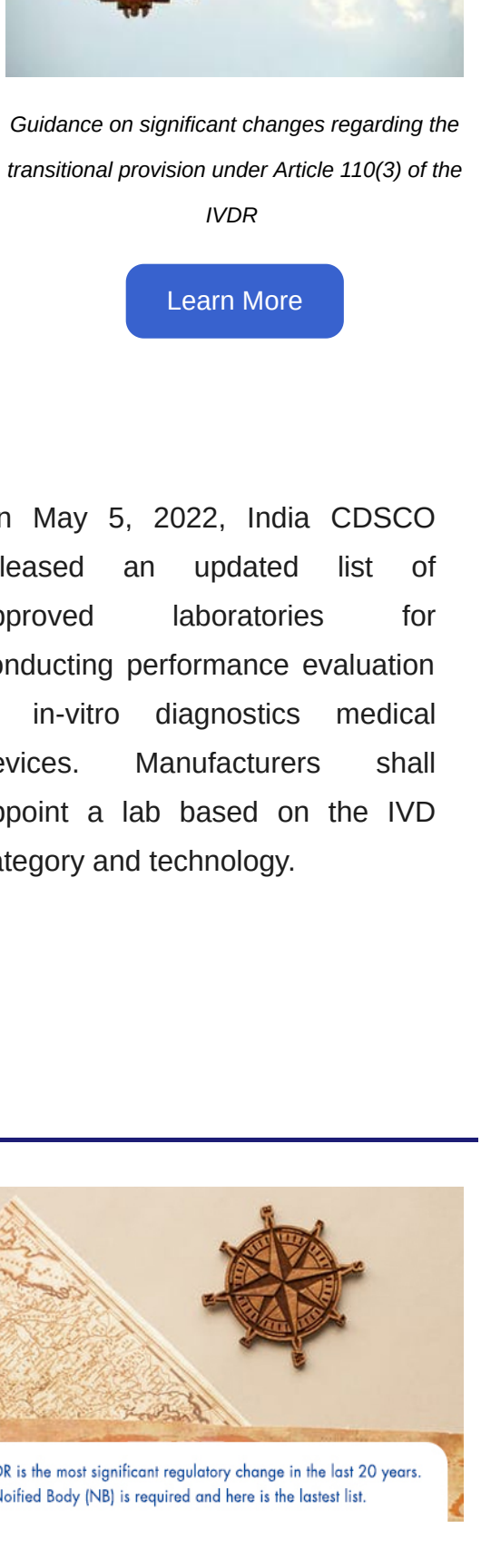
Plant your seedlings now!

With the warmer weather, rice is being planted in the fields. This is the time to start the process that would lead to a bountiful harvest. Get the latest information with Access-2-Healthcare's MedTech Gateway for May 2022.

AUSTRALIA

On May 3, 2022, Australia TGA released a factsheet which provides information regarding the regulation of digital mental health software. The factsheet allows industry stakeholders to assess and determine if their software is a medical device, and if yes, relevant regulatory requirements shall be adhered to.



Regulation of software-based medical devices

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MALAYSIA

Updated guidance document on Rules of Classification for General Medical Devices

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MDA released the second edition of MDA/GD/0009 Rules of Classification for General Medical Devices on May 9, 2022. The manufacturer must take into consideration all the rules in order to establish the proper classification for its device.

EUROPE

The European Commission released a guidance document on significant changes regarding the transitional provision under Article 110(3) of the IVDR on May 4, 2022. It is intended to provide clarification to industry stakeholders on the concept of "significant changes in the design and intended purpose".

Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR

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INDIA

List of laboratories for performance evaluation of IVDs

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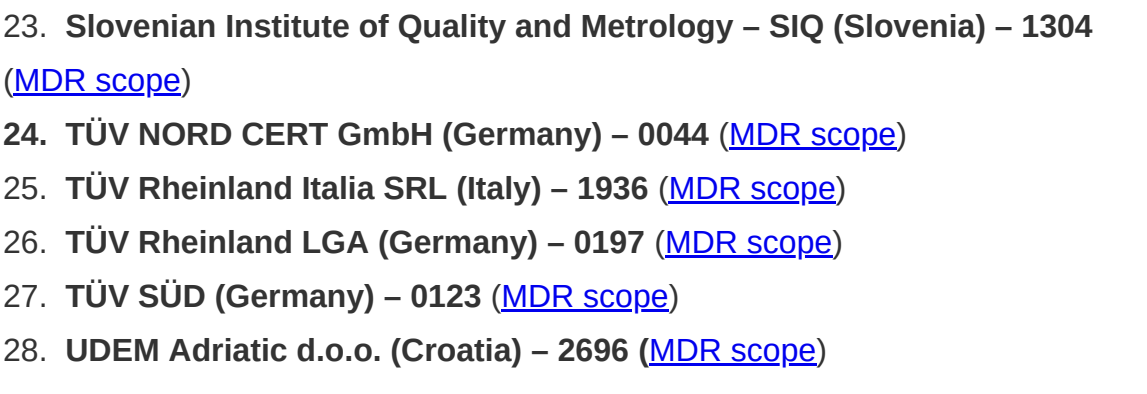
On May 5, 2022, India CDSCO released an updated list of approved laboratories for conducting performance evaluation of in-vitro diagnostics medical devices. Manufacturers shall appoint a lab based on the IVD category and technology.



Regulation (EU) 2017/745 on medical devices (MDR):

1. **3EC International (Slovakia) – 2265** (MDR scope)
2. **BSI (Netherlands) – 2797** (MDR scope)
3. **CE Certiso (Hungary) – 2409** (MDR scope)
4. **CERTIQUALITY S.r.l. – 0546** (MDR scope)
5. **DEKRA Certification (Germany) – 0124** (MDR scope)
6. **DEKRA Certification (Netherlands) – 0344** (MDR scope)
7. **DNV Product Assurance AS (Norway) – 2460** (MDR scope)
8. **DQS Medizinprodukte (Germany) – 0297** (MDR scope)
9. **Eurofins Expert Services Oy (Finland) – 0537** (MDR scope)
10. **Eurofins Product Testing Italy S.r.l. (Italy) – 0477** (MDR scope)
11. **GMED SAS (France) – 0459** (MDR scope)
12. **IMQ (Italy) – 0051** (MDR scope)
13. **Intertek Medical Notified Body AB (Sweden) – 2862** (MDR scope)
14. **Istituto Superiore Di Sanita' (Italy) – 0373** (MDR scope)
15. **ITALCERT SRL (Italy) – 0426** (MDR scope)
16. **KIWA CERMET ITALIA S.P.A (Italy) – 0476 (**MDR scope)
17. **Kiwa Dare B.V (Netherlands) – 1912 (**MDR scope)
18. **MDC Medical Device Certification (Germany) – 0483** (MDR scope)
19. **MEDCERT (Germany) – 0482** (MDR scope)
20. **NSAI (Ireland) – 0050** (MDR scope)
21. **SGS Belgium NV (Belgium) – 1639** (MDR scope)
22. **SGS FIMKO OY (Finland) – 0598** (MDR scope)
23. **Slovenian Institute of Quality and Metrology – SIQ (Slovenia) – 1304** (MDR scope)
24. **TÜV NORD CERT GmbH (Germany) – 0044** (MDR scope)
25. **TÜV Rheinland Italia SRL (Italy) – 1936** (MDR scope)
26. **TÜV Rheinland LGA (Germany) – 0197** (MDR scope)
27. **TÜV SÜD (Germany) – 0123** (MDR scope)
28. **UDEM Adriatic d.o.o. (Croatia) – 2696 (**MDR scope)

Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR):

1. 3EC International (Slovakia) – 2265 (IVDR scope)

2. **BSI (Netherlands) – 2797 (**IVDR scope)
3. **DEKRA Certification (Germany) – 0124** (IVDR scope)
4. **DEKRA Certification (Netherlands) – 0344** (IVDR scope)
5. **GMED SAS (France) – 0459** (IVDR scope)
6. **TÜV Rheinland LGA (Germany) – 0197 (**IVDR scope)
7. **TÜV SÜD (Germany) – 0123** (IVDR scope)

Withdrawals

1. **BSI Assurance (UK) – 0086**
2. **DQS Polska (Poland) – 2282**
3. **ECM (Germany) – 0481**
4. **GMED SAS (France) – 0459**
5. **Presafe (Denmark) – 0543**
6. **SGS United Kingdom Limited (UK) – 0120**

NEPAL

IVI, SmileGate, partners team up to vaccinate 28,000 people in Nepal

The International Vaccine Institute (IVI), in collaboration with SmileGate in Korea and Nepalese partners, will vaccinate 28,000 people against cholera to help prevent and control outbreaks in Nepal in May 2022. The project will vaccinate about 28,000 individuals including children in Rupani Rural Municipality in the southeastern region of Nepal to help prevent and control outbreaks of cholera and diarrheal diseases there. Diarrheal cases were detected in the municipality in late October 2021. On top of the COVID-19 pandemic, this outbreak of cholera and diarrheal diseases has further strained the local public health delivery mechanism in the area.

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UK

UK Health Security Agency signs agreement with Korea Disease Control and Prevention Agency

Dr. Dame Jenny Harries, Chief Executive of the UK Health Security Agency (UKHSA), today signed the memorandum of understanding (MoU) with Dr. Eunkyeong Jeong, Commissioner of the Korea Disease Control and Prevention Agency (KDCA). Since its launch in October 2021, UKHSA has been working closely with organisations across the world specialising in global health protection – it signed an MoU with the European Centre for Disease Prevention and Control (ECDC) in December.

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AUSTRALIA

Record investment in the future of Australia's health system

The Australian Government is investing in a stronger health system as part of our plan for a stronger future through a record $132 billion in 2022–23, increasing to $140 billion in 2025–26, with a total commitment of $537 billion over the next four years.

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SINGAPORE

Streamlining birth and death registration processes; digital certificates to replace physical certificates from 29 may 2022

From 29 May 2022, the birth and death registration processes will be made simpler, and digital birth and death certificates will be issued in place of physical certificates. This is part of the Government’s ongoing effort to streamline and digitalise services to serve citizens better

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UNITED KINGDOM

AMBLor® gains NICE Advice as Medtech Innovation Briefing

Today NICE published their Advice on **“AMBLor for identifying low-risk non-ulcerated early-stage cutaneous melanomas”**. This formal external review and publication is a significant step in getting AMBLor® adopted into clinical care pathways in the UK. It follows on from AMLo’s NICE AdviSeMe prize for AMBLor® in 2018. The MiB reviewed studies in 1,025 people with early-stage non-ulcerated melanoma and showed that *“AMBLor can identify low risk of disease progression in non-ulcerated Stage 1 and 2 melanomas. It is not suitable for identifying high risk melanomas.”*

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AUSTRALIA

Biodesign australia announce partnership

Texas Medical Center (TMC) and Biodesign Australia today announced a partnership aimed at advancing health and life science research through commercialization, innovation and research. TMC and Biodesign Australia will work collaboratively to facilitate opportunities between TMC Biodesign and programs within the Biodesign Australia network, and founders and entrepreneurs will be provided with access to talent, clinical trial activity, expanded funding opportunities and markets. The announcement builds on the TMC/Australia BioBridge, which was launched in 2018.

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JAPAN

AI Medical Service raises a total of 8 billion yen as the largest investment in Japanese companies in the Series C round with SoftBank Vision Fund 2 as the lead investor

AI Medical Service Inc has SoftBank Vision Fund 2 as the lead investor and existing investors Globis Capital Partners, WiL, LLC. We are pleased to announce the raising of a total of 8 billion yen in the Series C round in which the Investor Fund participates. SoftBank Vision Fund (“SVF”) is one of the world's largest technology funds, investing in AI-related companies, with a cumulative investment of $ 129.6 billion [1] from its establishment to the end of 2021. With this funding, AIM will deploy an AI-based endoscopic diagnosis support system (hereinafter referred to as "endoscopic AI") worldwide and accelerate the construction of a cloud platform for endoscopic AI.

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US

Texas medical center and biodesign Australia announce partnership

Texas Medical Center (TMC) and Biodesign Australia today announced a partnership aimed at advancing health and life science research through commercialization, innovation and research. TMC and Biodesign Australia will work collaboratively to facilitate opportunities between TMC Biodesign and programs within the Biodesign Australia network, and founders and entrepreneurs will be provided with access to talent, clinical trial activity, expanded funding opportunities and market access. The announcement builds on the TMC/Australia BioBridge, which was launched in 2018.

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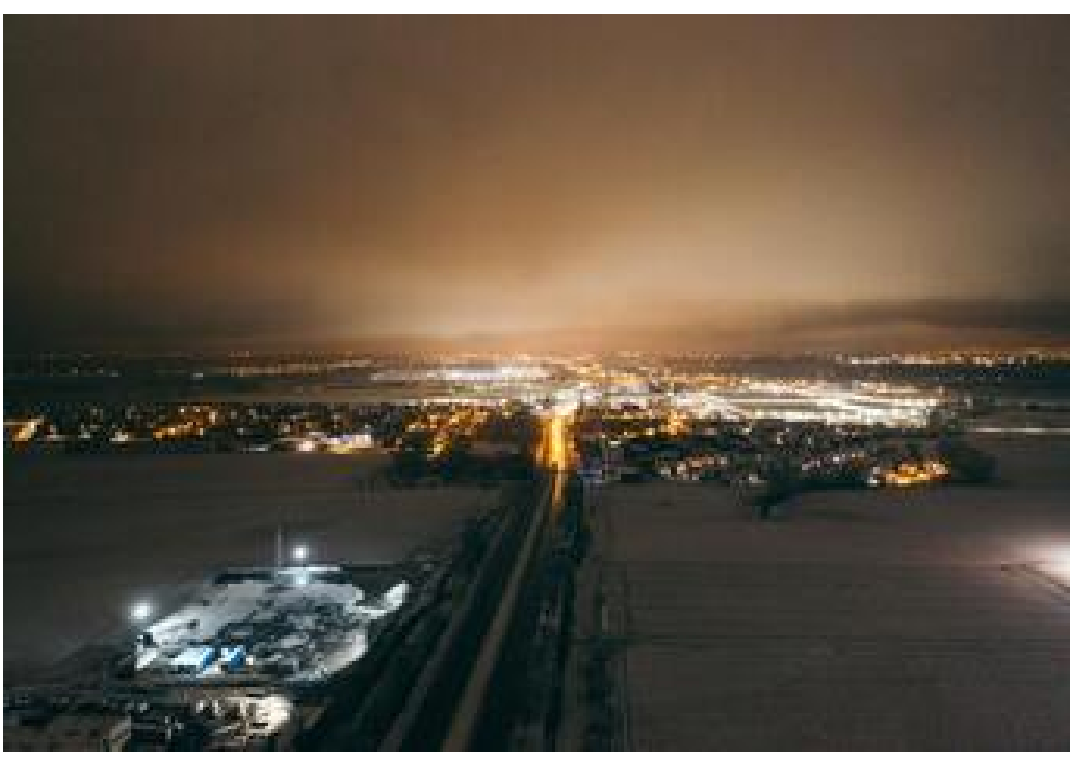
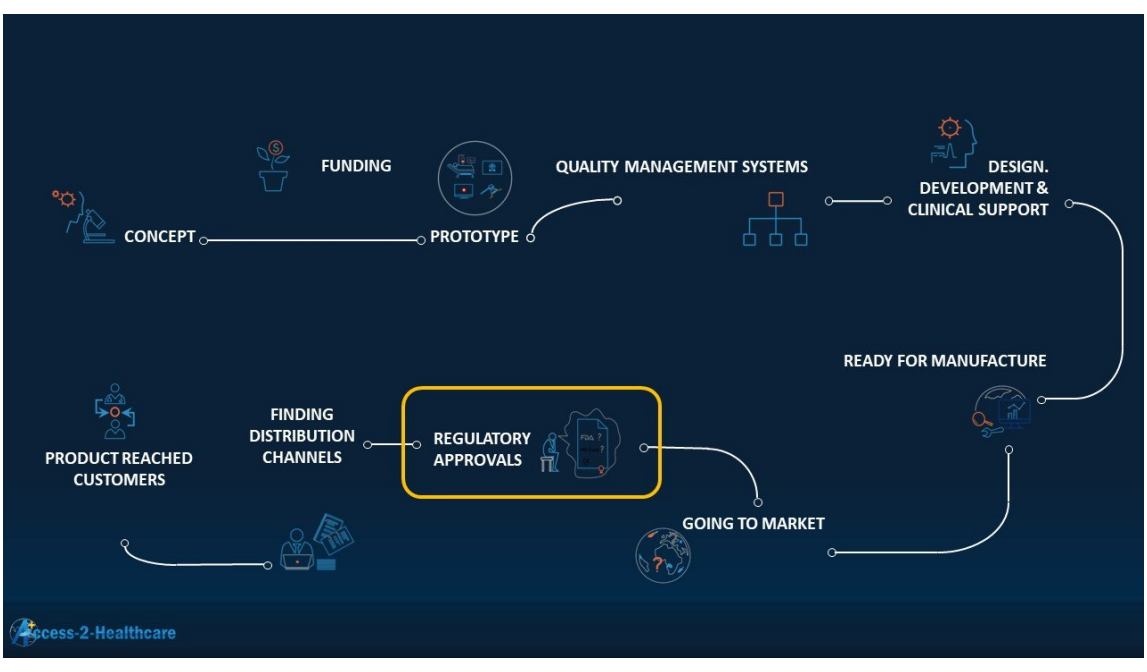
SINGAPORE



Avantor® Announces Investment in Manufacturing and Distribution Hub in Singapore to Serve Rapidly Growing Asia Pacific Biopharma Industry

Avantor, Inc. (NYSE: AVTR), a leading global provider of mission-critical products and services to customers in the life sciences, advanced technologies and applied materials industries, today announced it will create a new manufacturing and distribution hub in Singapore by integrating its existing distribution facility with new manufacturing operations. The new hub, which brings Avantor solutions closer to regional customers and strengthens global supply chain capabilities, will be fully operational early next year. "The Singapore Manufacturing and Distribution Hub will enable Avantor to better serve the fast-growing Asia Pacific Biopharma market by facilitating shorter lead times, enhancing supply chain security and increasing capacity in the region," said Christophe Couturier, Executive Vice President, AMEA, Avantor. "The hub will boost regional innovation and serve as an industry benchmark for Singapore and Asia Pacific's global quality and regulatory standards, and demonstrates Avantor's commitment to growing our presence in the region."

Learn More



Regulatory Approvals

Route A or B – which to take?

In one of our frequent introductory coffee sessions, one of our clients wanted to market their device only in one country, where there is clear market potential.

The device is manufactured in another country, and the client was interested in being the legal manufacturer. He proceeded to mention about the need to either find a way to market to that country via a direct regulatory pathway, or going through one of the 5 reference countries first, then ‘instantly gain approval’.

This was explained in a training session in Japan some months ago because some device manufacturers asked the same question.

While it is understood that it is easier to use CE mark or an FDA approval to register medical device compared with the full evaluation route, will it also be less expensive? Well, is it?

There are 5 overseas reference regulatory agencies which can be used as a basis of evaluation (EU EMA, Australia TGA, Health Canada, US FDA, or Japan MHLW). If the product has been approved in any of the 5 above, it is true that the evaluation route will be shorter compared to full evaluation, typically about 50% reduction. However, gaining approval in those 5 reference agencies also take time, money, and effort.

There is also an incorrect assumption that having a CE mark or FDA approval will mean instant or very fast approval by country regulators. Another factor is the quality of the country specific dossier.

If that is not correctly put together, the time gained becomes the time lost.

Unless there is more than one country that may benefit from registering in the 5 reference agencies, it is much more streamlined to register locally, gain some revenue, then fund the registration in the 5 reference countries.

Another factor is the need to be the legal manufacturer. There are several reasons, such as the need to enter certain markets where it would be difficult for the original (physical) manufacturer to market themselves due to policies or politics, or even competition. Another reason may be for branding/marketing purposes. Therefore, it was ascertained that there is a need to, and as well to assign the country of origin to the legal manufacturer (where every IMPORTING

country has their definition). It is about overall time to market, opportunity cost, and the efforts.

Proper regulatory pathway planning must be conducted together with the sales and marketing team, always.

May is the right month to get out there and travel (physically and virtually!). Here are some events that are on this month.

2022 PDA Medical Devices and Connected Health Conference
May 16-17, 2022
Dublin, Ireland
https://shorturl.ae/HTbTk

MEDICAL FAIR INDIA 2022
May 20-22, 2022
Mumbai, India
https://shorturl.ae/wuXhL

Southeast Life Sciences
May 25-27, 2022
Atlanta, GA
https://southeastlifesciences.org/

5th Global Conference on Pharma Industry and Medical Devices (GCPIMD-2022)
May 24-25, 2022
Berlin, Germany
http://www.gcpimd.igrnet.org/205/germany/

Changes to the HCPCS Application Process & Impact on AI Coding and Reimbursement
May 18, 2022
MDMA (Webinar)
https://shorturl.ae/x8eN9

Regulatory Transformation Symposium
May 26,2022
APACMed (Virtual Event)
https://shorturl.ae/tNdui

INTERPHEX 2022
May 24-26, 2022
New York, NY
https://www.interphex.com/en-us.html

Access-2-Healthcare

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