

"To be inspirational you don't have to save lives or win medals"

Queen Elizabeth II (1926-2022)



Passing...

We have witnessed the end of a long reign of the Queen. In this time of change, [Access-2-Healthcare](#) will continue supporting you and your MedTech endeavours. Check out this month's MedTech Gateway to stay inspired.

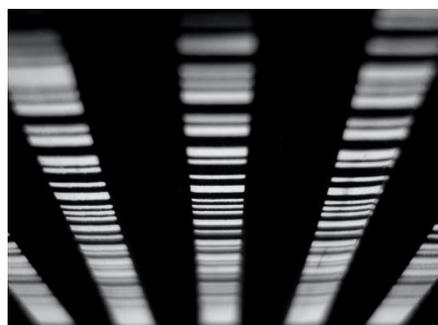


REGULATORY ROUNDUP

The latest regulatory updates for the medical devices industry



AUSTRALIA



Consultation on considerations for implementing UDI regulatory framework

Australia TGA is seeking views from industry stakeholders on implementation of UDI regulatory framework. They include the impact of accepting EU and US compliant UDI labels, scope and exemptions, fees, supporting documentation and even regulatory burden. Respondents are welcome to provide inputs by Oct 11, 2022.

[Learn More](#)

AUSTRALIA

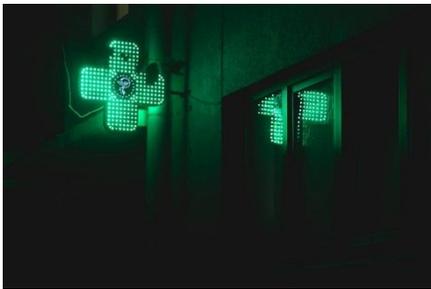
Australia's Department of Health has announced "Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022," which amends "Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018," allowing a copy of the entry in the Singapore Register of Health Products to be accepted by the Therapeutic Goods Administration in support of an application for inclusion in the Register as an alternative to the existing conformity assessment documents.



Entry in SMDR can be considered as preliminary assessment requirement for application to ARTG

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EUROPE



Notified body capacity and availability of medical devices and IVDs

On Aug 26, 2022, an MDCG Position Paper on the Notified body capacity and availability of medical devices and IVDs was released. It lists the actions to enhance notified body capacity, access to notified bodies and manufacturers' preparedness to facilitate transition to the MDR/IVDR and to avoid shortage of medical devices.

[Learn More](#)

THAILAND

All documents in the e-submission process will now be screened by Thai FDA before the applicant pays the submission fees. Depending on the risk classification of the device, the average turnaround time for approval takes 150-200 days.



Updates on e-submission process

[Learn More](#)

MALAYSIA



Guidance on harmonised borderline products in ASEAN

On Sep 5, 2022, Malaysia MDA released a guidance document which helps manufacturers understand, based on ASEAN harmonisation, whether medical devices are classified as borderline products (medical device or non-medical device) based on their intended purpose.

[Learn More](#)

HONG KONG

With effect from Oct 1, 2022, certain medical devices being purchased for use in the services of DH shall preferably be listed under the Medical Device Administrative Control System (MDACS).

[Learn More](#)



New procurement requirement for medical devices being purchase by Department of Health (DH) Hong Kong

INDIA



Updated list of notified bodies registered with CDSCO

India CDSCO released an updated list of notified bodies who are authorised to carry out audit of manufacturing site under the provisions of Medical Devices Rules 2017.

[Learn More](#)



DESIGNATED NBs

Here is the latest list of Notified Bodies



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

1. 3EC International (Slovakia) – 2265
2. BSI (Netherlands) – 2797
3. BUREAU VERITAS (Italy) – 1370
4. Berlin Cert Pruf (Germany) - 0633
5. CE Certiso (Hungary) – 2409
6. CENTRO NACIONAL DE CERTIFICACION (Spain) – 0318
7. CERTIQUALITY S.r.l. – 0546
8. DEKRA Certification (Germany) – 0124
9. DEKRA Certification (Netherlands) – 0344
10. DNV Product Assurance AS (Norway) – 2460
11. DQS Medizinprodukte (Germany) – 0297
12. Eurofins Electric & Electronics Oy (Finland) – 0537
13. Eurofins Product Testing Italy S.r.l. (Italy) – 0477
14. GMED SAS (France) – 0459
15. IMQ (Italy) – 0051
16. Intertek Medical Notified Body AB (Sweden) – 2862
17. Istituto Superiore Di Sanita' (Italy) – 0373
18. ITALCERT SRL (Italy) – 0426
19. KIWA CERMET ITALIA S.P.A (Italy) – 0476
20. Kiwa Dare B.V (Netherlands) – 1912
21. MDC Medical Device Certification (Germany) – 0483
22. MEDCERT (Germany) – 0482
23. NSAI (Ireland) – 0050
24. SGS Belgium NV (Belgium) – 1639
25. SGS FIMKO OY (Finland) – 0598
26. Slovenian Institute of Quality and Metrology – SIQ (Slovenia) – 1304
27. TUV NORD Polska (Poland) – NB 2274
28. TÜV NORD CERT GmbH (Germany) – 0044
29. TÜV Rheinland Italia SRL (Italy) – 1936
30. TÜV Rheinland LGA (Germany) – 0197
31. TÜV SÜD (Germany) – 0123
32. UDEM Adriatic d.o.o. (Croatia) – 2696

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

1. 3EC International (Slovakia) – 2265
2. BSI (Netherlands) – 2797
3. DEKRA Certification (Germany) – 0124
4. DEKRA Certification (Netherlands) – 0344
5. GMED SAS (France) – 0459
6. TÜV Rheinland LGA (Germany) – 0197
7. TÜV SÜD (Germany) – 0123

Withdrawals

1. 1BSI 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



IN-COUNTRY FOCUS

What are the latest in healthcare policies today?

UNITED KINGDOM



7 new community diagnostic centres to offer more patients life-saving checks

Seven new community diagnostic centres (CDCs) will open to help bust the COVID backlogs, diagnose patients more quickly and meet future demands on the NHS, the Health and Social Care Secretary has confirmed.

[Learn More](#)

SINGAPORE



NTU Singapore, A*STAR, and NHG launch S\$15 million BioMedtech incubator

To facilitate the clinical adoption of new technologies that will create value for patients, Nanyang Technological University, Singapore (NTU Singapore), Agency for Science, Technology and Research (A*STAR), and National Healthcare Group (NHG) today launched co11ab Novena (co11ab), an incubator to support biomedical technology (BioMedtech) start-ups make the leap from research and development into commercialisation of their innovations.

[Learn More](#)

UNITED STATES



HHS Approves Nation's First Medicaid Mobile Crisis Intervention Services Program, To Be Launched in Oregon

The new Medicaid option, created through President Biden's American Rescue Plan, will strengthen behavioral health care and make our communities safer by ensuring law enforcement can focus more on accountable policing and less on work that's more appropriate for mental health counselors or social workers.

[Learn More](#)

EUROPE



A new cancer screening method could revolutionise treatment

Cancer doctors, care providers and payers need to get ready for a major shift in early cancer detection that will affect almost every stage of cancer diagnosis and treatment. New data supporting the accuracy of multi-cancer early detection (MCED) blood testing (1), presented at the ESMO Congress 2022, have major implications for future cancer care provision, said Fabrice André, ESMO 2022 Scientific Co-Chair. In line with nationwide efforts to combat diabetes, the National Healthcare Group (NHG) and Tanoto Foundation are spearheading a Diabetes Reversal1 Programme in Singapore. The Programme seeks to control blood sugar levels in diabetes patients through behavioural change without the need for medication or surgery. Co-funded by a S\$2.6 million contribution from Tanoto Foundation and S\$1 million from the NHG Fund, this initiative will boost diabetes research in primary care and the community.

[Learn More](#)



INDUSTRY INSIGHT

Announcements from countries where we have a presence

EUROPE

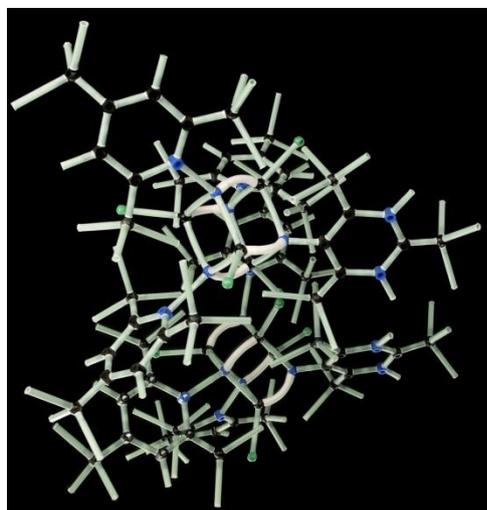


Brainomix's AI Software to be Rolled Out Across Hungary's Entire National Healthcare System to Improve Stroke Care

Brainomix, the AI-powered medtech solutions company, announced that it has been awarded the national tender in Hungary to deploy its AI stroke imaging software across all stroke centers in Hungary as part of the National Institute for Health Development initiative to improve stroke care.

[Learn More](#)

AUSTRALIA



New molecule chip changing the face of modern manufacturing

University of Queensland researchers have pioneered a new chemical process to manufacture the molecules that are the building blocks for lifesaving medicines, vaccines and energy storage materials.

Professor Matt Trau from UQ's Australian Institute for Bioengineering and Nanotechnology (AIBN) has been awarded an ARC Laureate Fellowship worth \$2.9 million to further understand and develop the process.

[Learn More](#)

UNITED KINGDOM



GlucoRx announces world's first Multi-Sensor Non-Invasive glucose monitoring

GlucoRx and Cardiff University are set to bring out the world's first multi-sensor non-invasive continuous glucose monitor (CGM) to herald a new era of needle-free monitoring for people with diabetes.

The GlucoRx BioXensor™ uses patented radio frequency technology alongside a multiple sensor approach to measure blood glucose levels every minute reliably, accurately, and non-invasively.

[Learn More](#)

SINGAPORE



Docquity raises US\$44 million in series C round led by Itochu Corporation

Singapore-based Docquity, Southeast Asia's largest community of healthcare professionals, announced today that it has raised a total of US\$44 million in its Series C financing round, led by existing investor Japan's Itochu Corporation with US\$32 million.

Other investors supporting this round included iGlobe Partners, Alkemi, Global Brain, KDV and Infocom. To date, Docquity has raised US\$57.5 million.

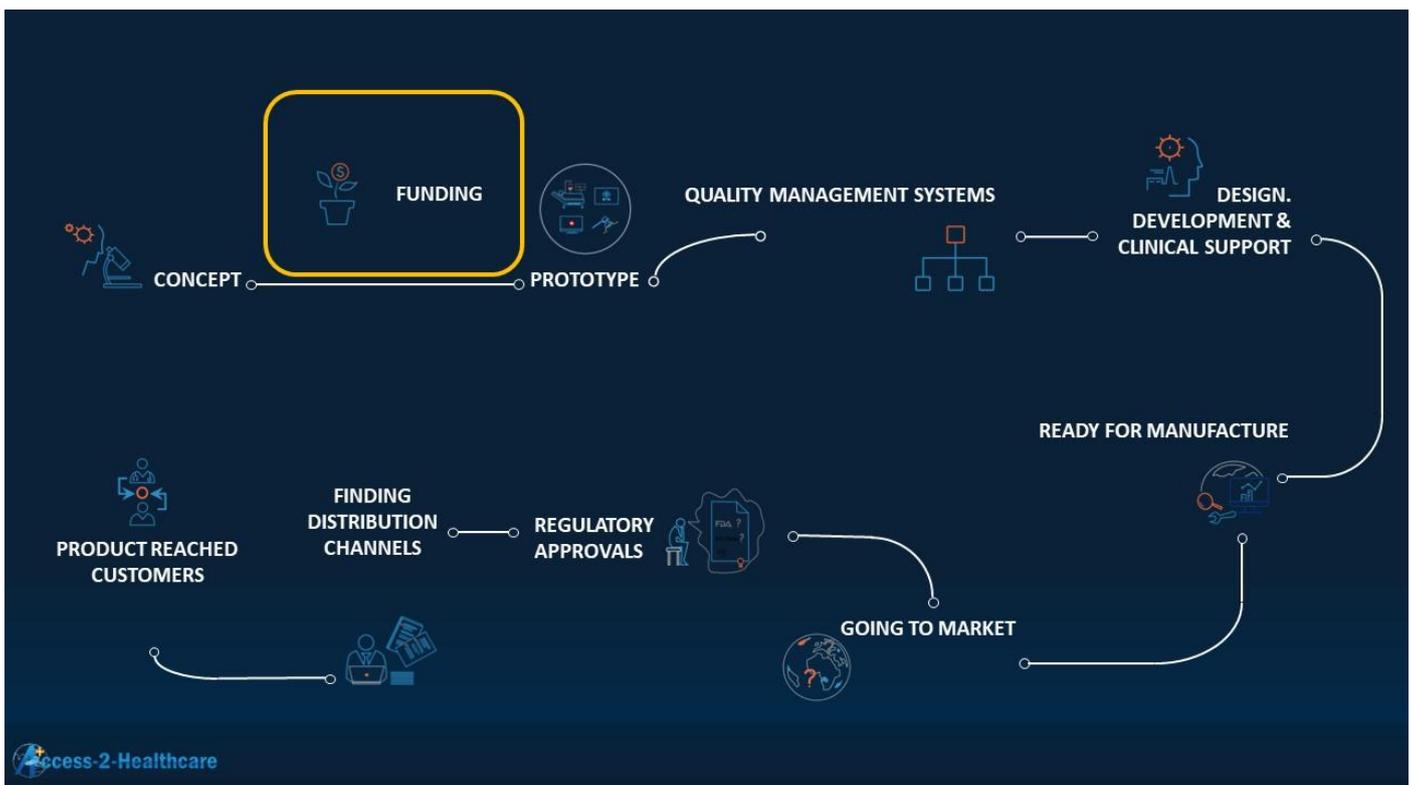
[Learn More](#)



PRODUCT COMMERCIALISATION

Articles to help your journey in commercialisation.





Finding the “Lead Dog”

Getting the lead investor to believe in you.

Most MedTech start-ups know the basics:

- Find an investor that understands the complexities of MedTech
- Have an investor that can fund the ticket size or part of it
- Investors provides more than just funding, but also network, resources

Let us focus on all these 3 points, but in relative sub-sets

#1 “.. understands the complexities of MedTech...”

Not just the complexities (clinical workflow, challenging market segment, regulatory, reimbursement schemes), a start-up needs to understand the portfolio the investor is trying to build, and its risk appetite. For example, if you are working on an implant, it is not appropriate to source for an investor that had been used to AI/ML software where the MVP comes out far quicker. The start-up must have a product that would complement or augment the investor’s portfolio. This drives the motivation for the investor to take the lead.

#2 “..investor ..fund... part of it”

Not often would one investor fund the entire round, therefore the lead investor as well – they would perhaps be able to fund 25-30% of your total ask. But that first investor is all that matters, as it sends a signal for the ‘herd instinct’ to kick in.

#3 “...network, resources”

Investors may have partners or consultants that have the appropriate network for the start-up to scale. This involves understanding the various members of the fund and their backgrounds, as well as the existing

portfolio. The investor may be a large corporate, in which the network and resources are fairly predictable. Again, it leverages on the fact that the investor feels that this start-up is a 'hit' because not only is it affordable, and fits the investor's portfolio, it also leverages the network of the investor to increase the chance of scaling up and success.

The pool of investors interested in MedTech is small, finding a suitable one increases the degree of difficulty. Oftentimes both investor and start-up fall into the common trap: No, not the start-up valley of death, but impatience. Therefore, being patient to chance upon or being referred to the right lead investor takes time. But once there is a fit, and with the follow-on investors also latching on to the lead investor's choice, there is a good chance of completing the funding round.



Great Touch



We finally get to be in touch – literally. Medical Fair Asia returns to Singapore The 14th edition was all about reimagining the marketplace amidst an evolving landscape.

The new experience – a live 3-day exhibition in Marina Bay Sands, Singapore – ensured exhibitors and visitors can continue networking and doing business. The event brought together a high-quality audience from the healthcare markets of Asia, and included the Start-Up Park, Community Care Pavilion – with a special focus on Mental Health, and the debut of the all-new Pandemic Management zone.

[Access-2-Healthcare](#) has been attending Medical Fair Asia since 2016, and interestingly some of the people we had met back then are still in contact with us today.

[Learn More](#)



UPCOMING EVENTS



***Perhaps there is place that you are interested in as your next vacation destination?
Check it out while attending these events!***

[Medicall 2022 - 30th India's Medical Equipment Exhibition \(New Delhi\)](#)

September 17-19, 2022

[Medical Technology Ireland Expo and Conference](#)

September 21-22, 2022
Galway, Ireland

[API China 2022](#)

September 27-29, 2022
Qingdao, China

[31th International Medical Exhibition PUBLIC HEALTH 2022](#)

October 5-7, 2022
Kyiv, Ukraine

[Medical Japan Tokyo](#)

October 12-14, 2022
Makuhari Messe (Chiba), Japan

[BioJapan 2022](#)

October 12-14, 2022
Yokohama, Japan

[BioJapan](#)

[MEDEX 2022 – Myanmar's International Medical & Pharmaceutical Equipment & Supply Exhibition](#)

October 12-14, 2022
Yangon, Myanmar

The logo features a large blue letter 'A' with a white arrow pointing right through its center. The 'A' is superimposed on a light blue globe showing the Americas. A yellow medical cross is positioned at the top right of the 'A'.

Access-2-Healthcare



Our mailing address is: helpme@access2hc.com

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