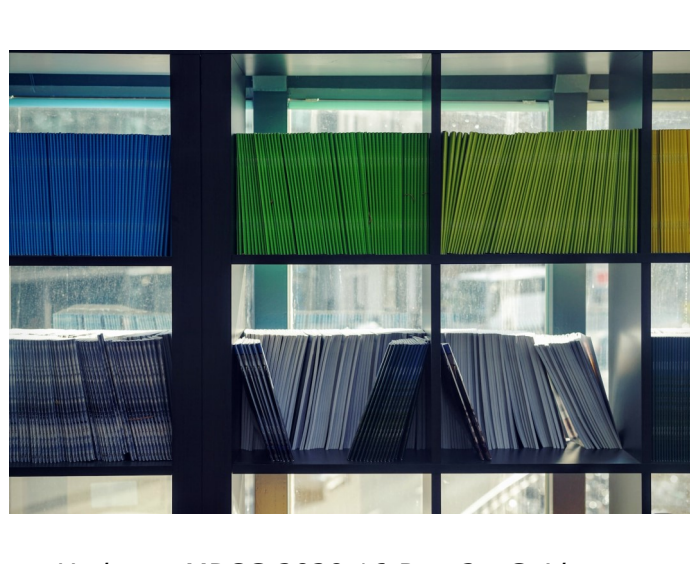
Happy 50th Issue!

Have you noticed the cake with candles?

Welcome to the 50th issue of Access-2-Healthcare's MedTech Gateway. We have been around for 8 years and hope to continue supporting you for many years to come!

EUROPE

The Directorate-General for Health and Food Safety has issued guidance on classification rules for in vitro diagnostic medical devices under Regulation (EU) 2017/746



Update - MDCG 2020-16 Rev.2 - Guidance on classification rules for in vitro diagnostic medical devices under Regulation (EU) 2017/746 - February 2023

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SINGAPORE

Public consultation for the proposed framework and implementation of the cybersecurity labelling scheme for medical devices, CLS(MD)

It was announced at the Singapore International Cyber Week 2022 that the Ministry of Health (MOH), Cyber Security Agency of Singapore (CSA), Health Sciences Authority (HSA), and the Integrated Health Information Systems (IHiS) has collaborated to develop and roll out the Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)].

The consultation window will be from 25 January 2023 to 3 March 2023

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CHINA

China's National Medical Products Administration (NMPA) released its annual medical device registration report, starting with an overview of products related to tackling the Covid-19 pandemic and other topics (report in Chinese)

National Medical Products Administration (NMPA) releases 2022 medical device registration report

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UNITED KINGDOM

List of manufacturers and their medical devices which have been granted an exemption by the MHRA

To ensure transparency around the supply of medical devices in the UK, the Medicines and Healthcare products Regulatory Agency is now providing a list of manufacturers and devices granted an exceptional use application. They will also provide a list of recently expired, withdrawn or cancelled authorisations for a 2 month period.

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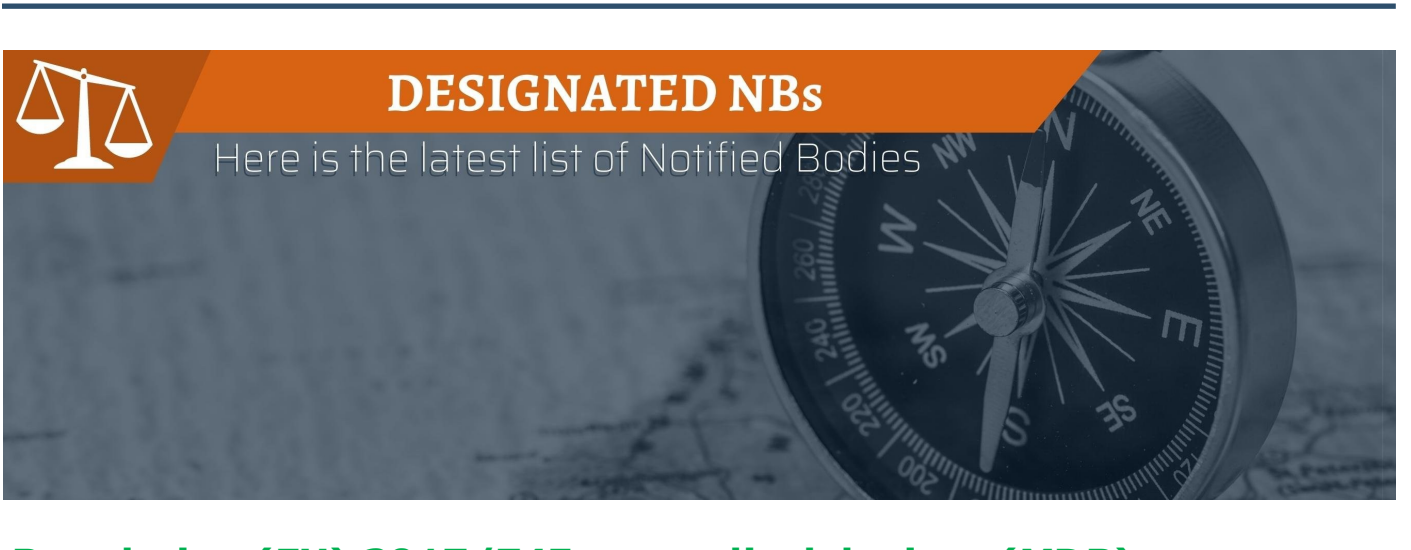


Regulation (EU) 2017/745 on medical devices (MDR):

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 CERTIFICATION (Spain) – 0318
7. CERTIQUALITY S.r.l. – 0546
8. DEKRA Certification (Germany) – 0124
9. DEKRA Certification (Netherlands) – 0344
10. DNV MEDCERT GMBH (Germany) - 0482
11. DNV Product Assurance AS (Norway) – 2460
12. DQS Medizinprodukte (Germany) – 0297
13. ENTE Certificazione Macchine SRL (Italy) – 1282
14. Eurofins Electric & Electronics Oy (Finland) – 0537
15. Eurofins Product Testing Italy S.r.l. (Italy) – 0477
16. GMED SAS (France) – 0459
17. ICIM S.P.A (Italy) – 0425
18. IMQ (Italy) – 0051
19. Institut Pro Testovani A Certifikaci (Czech Republic - 1023
20. Intertek Medical Notified Body AB (Sweden) – 2862
21. Istituto Superiore Di Sanita' (Italy) – 0373
22. ITALCERT SRL (Italy) – 0426
23. KIWA CERMET ITALIA S.P.A (Italy) – 0476
24. Kiwa Dare B.V (Netherlands) – 1912
25. MDC Medical Device Certification (Germany) – 0483
26. NSAI (Ireland) – 0050
27. Polskie Centrum Badan I (Poland) - 1424
28. SGS Belgium NV (Belgium) – 1639
29. SGS FIMKO OY (Finland) – 0598
30. SLG Pruf and Zertifizierungs (Germany) - 0494
31. Slovenian Institute of Quality and Metrology – SIQ (Slovenia) – 1304
32. TUV NORD Polska (Poland) – NB 2274
33. TÜV NORD CERT GmbH (Germany) – 0044
34. TÜV Rheinland Italia SRL (Italy) – 1936
35. TÜV Rheinland LGA (Germany) – 0197
36. TÜV SÜD (Germany) – 0123
37. UDEM Adriatic d.o.o. (Croatia) – 2696

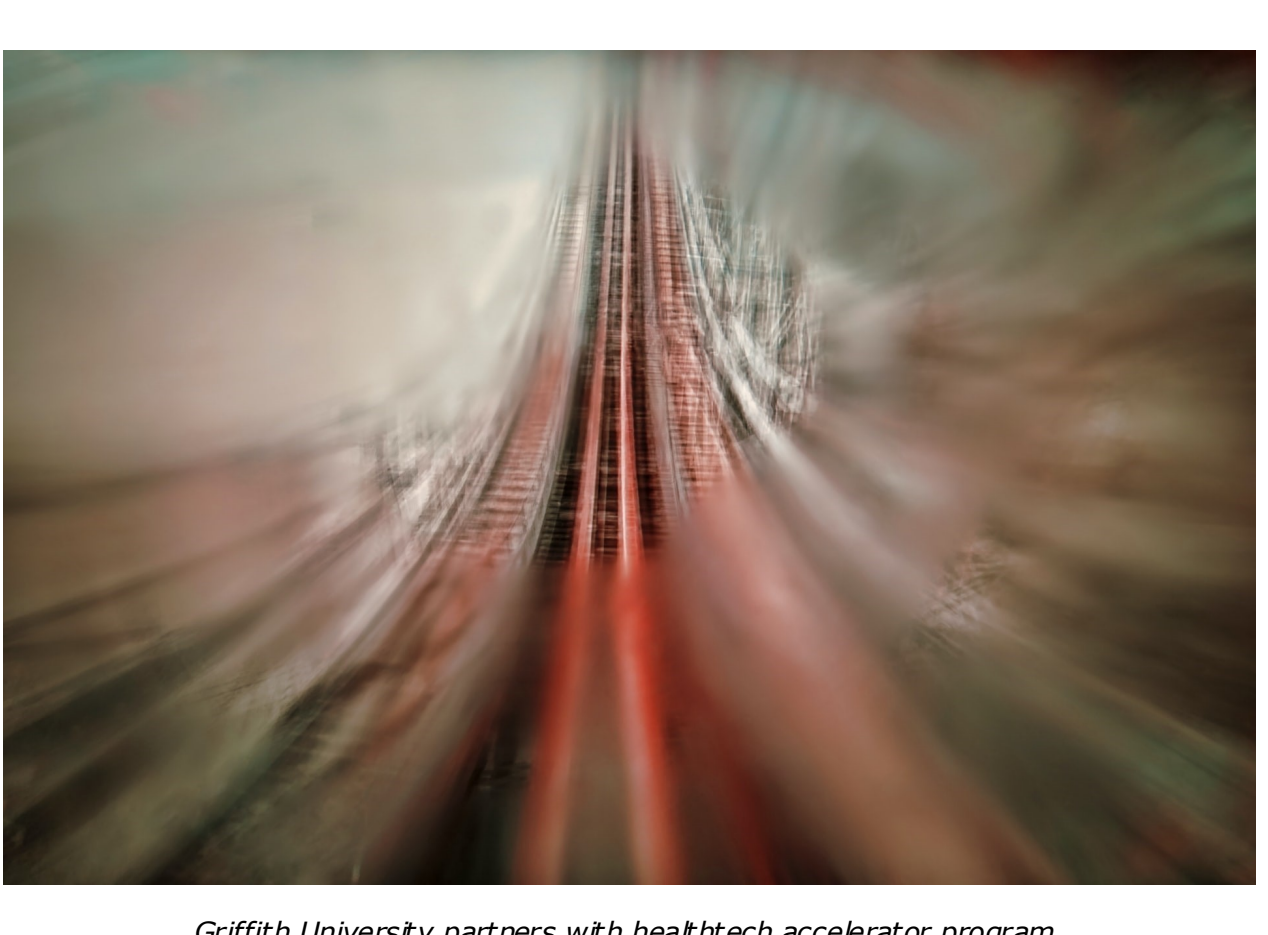
Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR):

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. MDC Medical Device Certification (Germany) – 0483
7. QMD Services (Austria) – 2962
8. TÜV Rheinland LGA (Germany) – 0197
9. TÜV SÜD (Germany) – 0123

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**

AUSTRALIA



Griffith University partners with healthtech accelerator program

Griffith University has committed to a three-year partnership with a leading health technology accelerator program based within the Gold Coast Health and Knowledge Precinct.

The LuminaX Healthtech Accelerator is a 14-week innovation program that fast-tracks commercialisation and market-readiness for up to 10 Australian health technology startups each year. Under the agreement, the chosen startups will be mentored by Griffith's globally regarded health and science academics and access the university's cutting-edge research facilities and resources.

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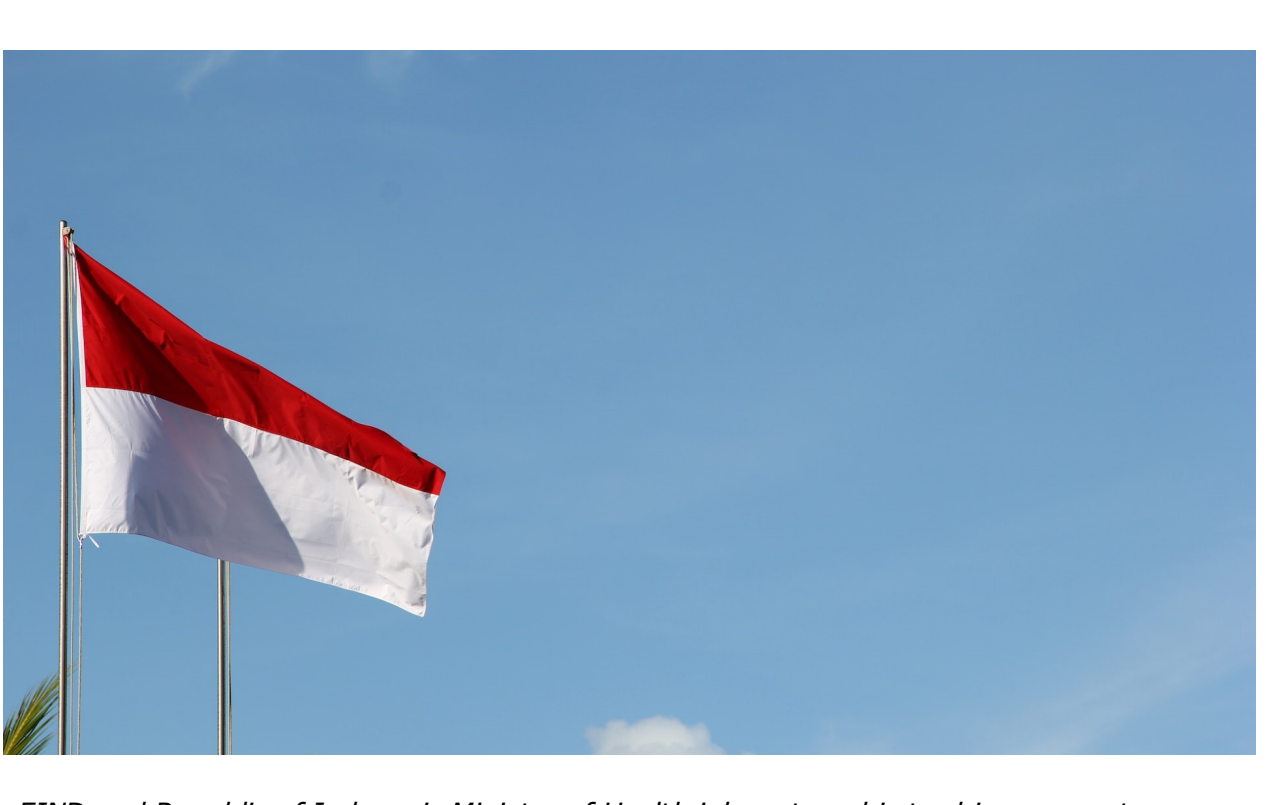
INDONESIA

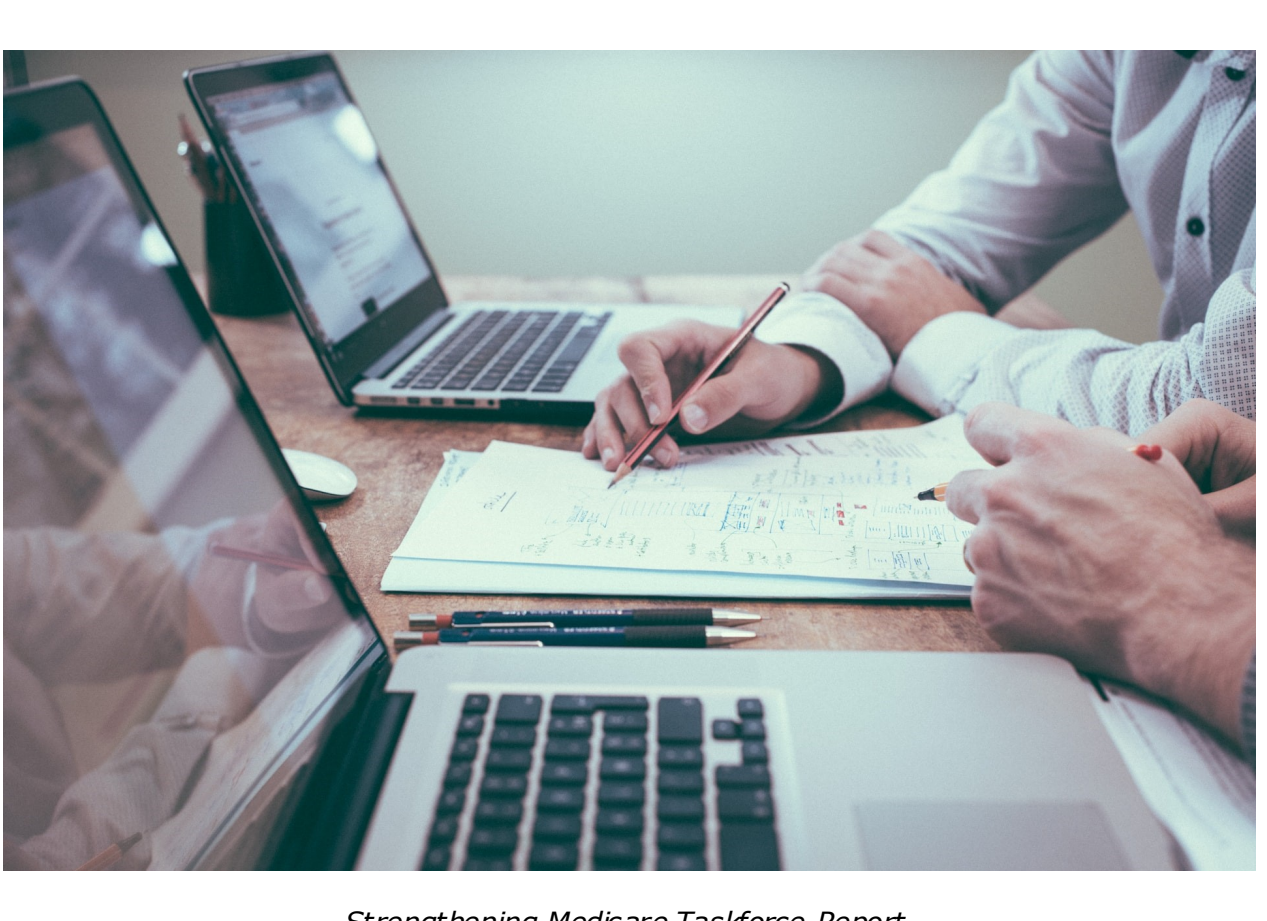


FIND and Republic of Indonesia Ministry of Health ink partnership to drive access to essential diagnostic tests

FIND and Kementerian Kesehatan Republik Indonesia (Ministry of Health of the Republic of Indonesia; MoH) announced that a formal memorandum of understanding (MOU) has been signed for a strategic collaboration that will expand access to essential diagnostics in the country. The partnership will focus on diagnostic testing to strengthen primary care and boost health system resilience in the country, building on the great strides already made to achieve universal health coverage – health for all – and to enhance health security.

Learn More

AUSTRALIA



Strengthening Medicare Taskforce Report

The Australian Government released the report of the Strengthening Medicare Taskforce on 3 February 2023. The Australian Government has committed $750 million to deliver the highest priority investments in primary care, in line with the recommendations of the Strengthening Medicare Taskforce.

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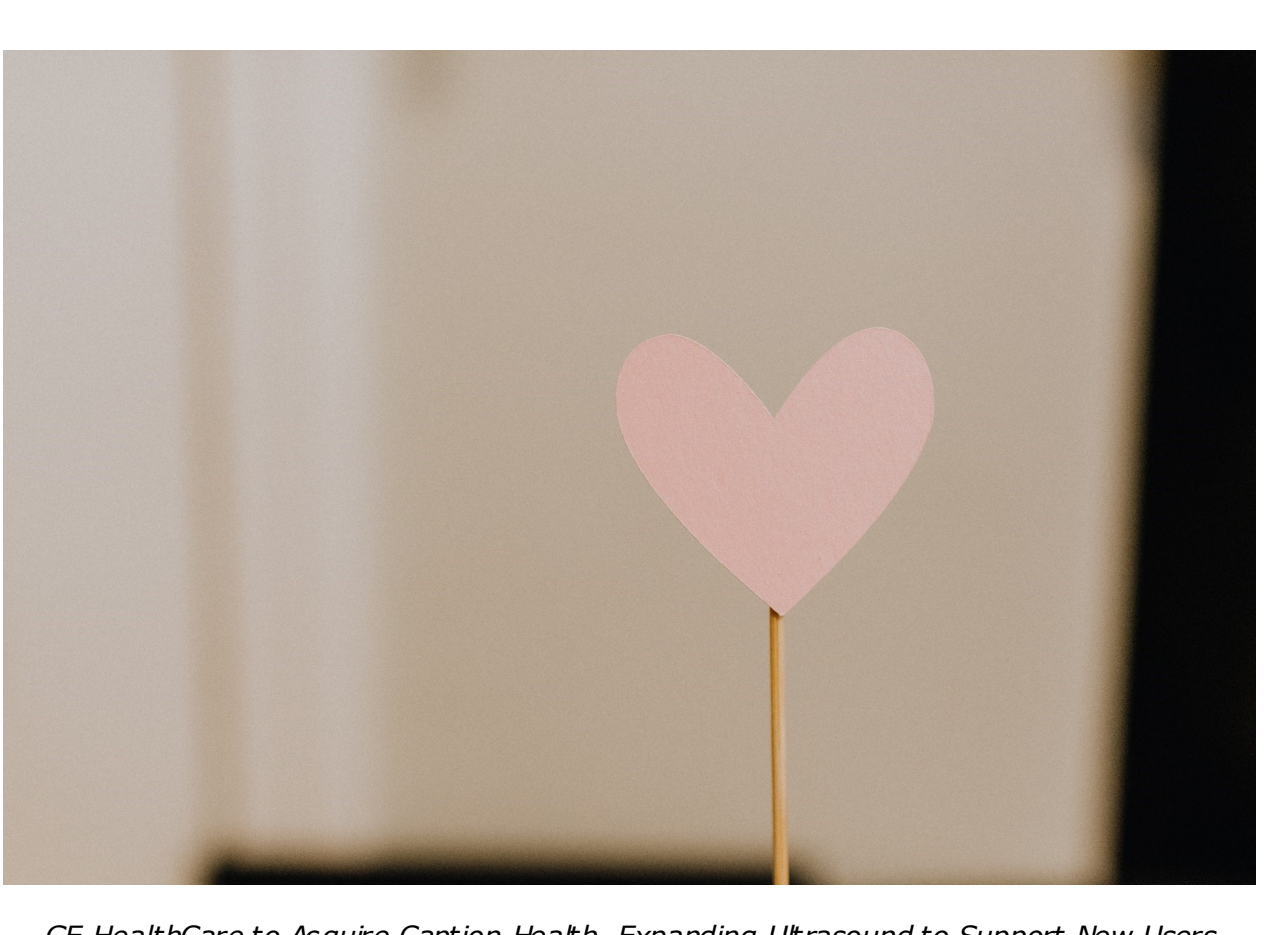
UNITED STATES



GE HealthCare to Acquire Caption Health, Expanding Ultrasound to Support New Users Through FDA-Cleared, AI-Powered Image Guidance

GE HealthCare (Nasdaq: GEHC), a leading global precision care innovator, announced that it has signed an agreement to acquire Caption Health, Inc., a privately owned artificial intelligence (AI) healthcare leader that creates clinical applications to aid in early disease detection, using AI to assist in conducting ultrasound scans. With Caption AI applications, ultrasound examinations can be easier and faster, enabling a broader set of healthcare professionals to conduct basic echocardiogram exams.

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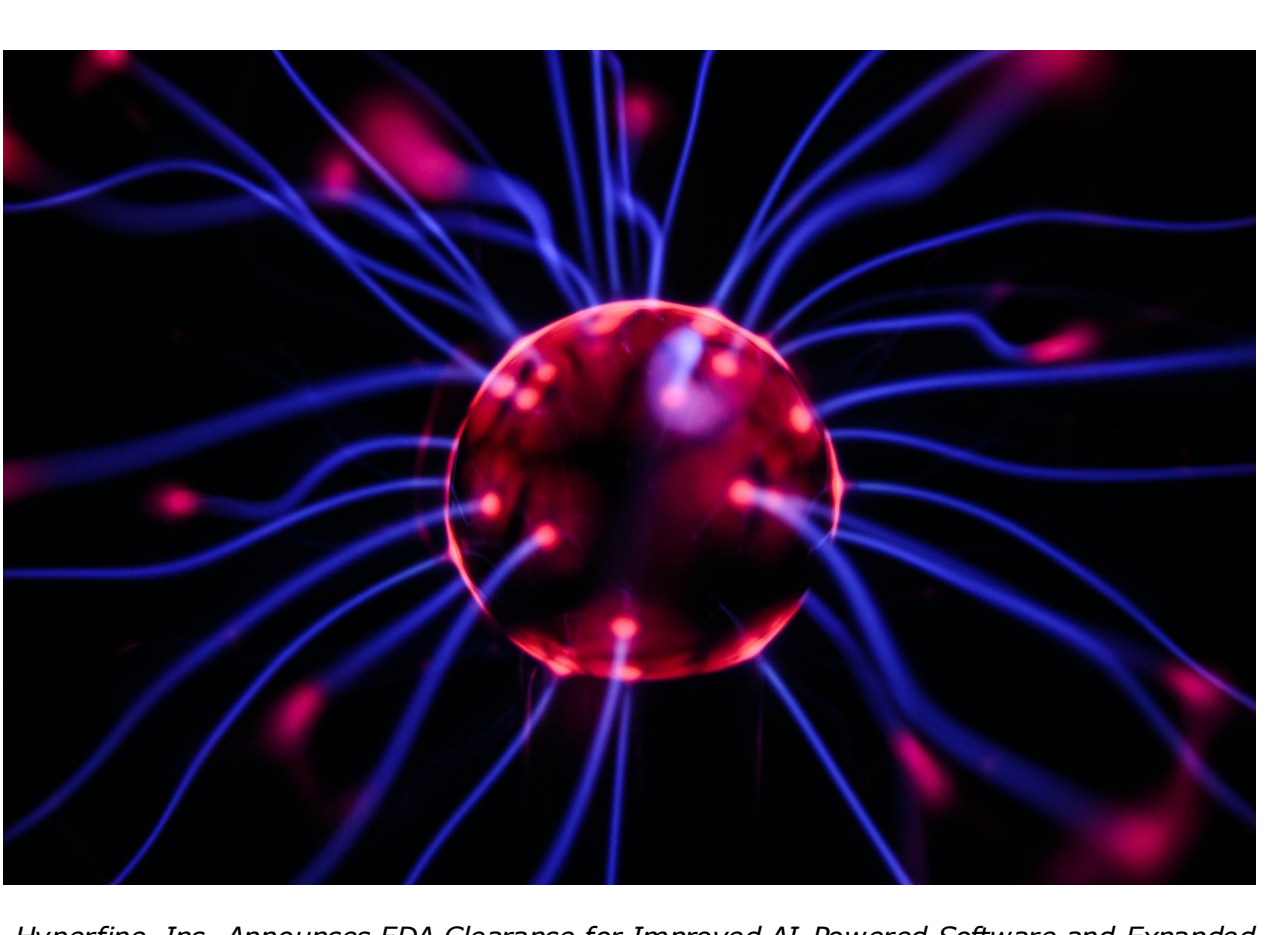
UNITED STATES



Hyperfine, Inc. Announces FDA Clearance for Improved AI-Powered Software and Expanded Field of View for the Swoop® Portable MR Imaging® System

Hyperfine, Inc., the groundbreaking medical device company that created the Swoop® system, the world's first FDA-cleared portable magnetic resonance imaging (MRI) device for imaging of the brain, today announced the U.S. Food and Drug Administration (FDA) 510(k) clearance and launch of the company's upgraded AI-powered software.

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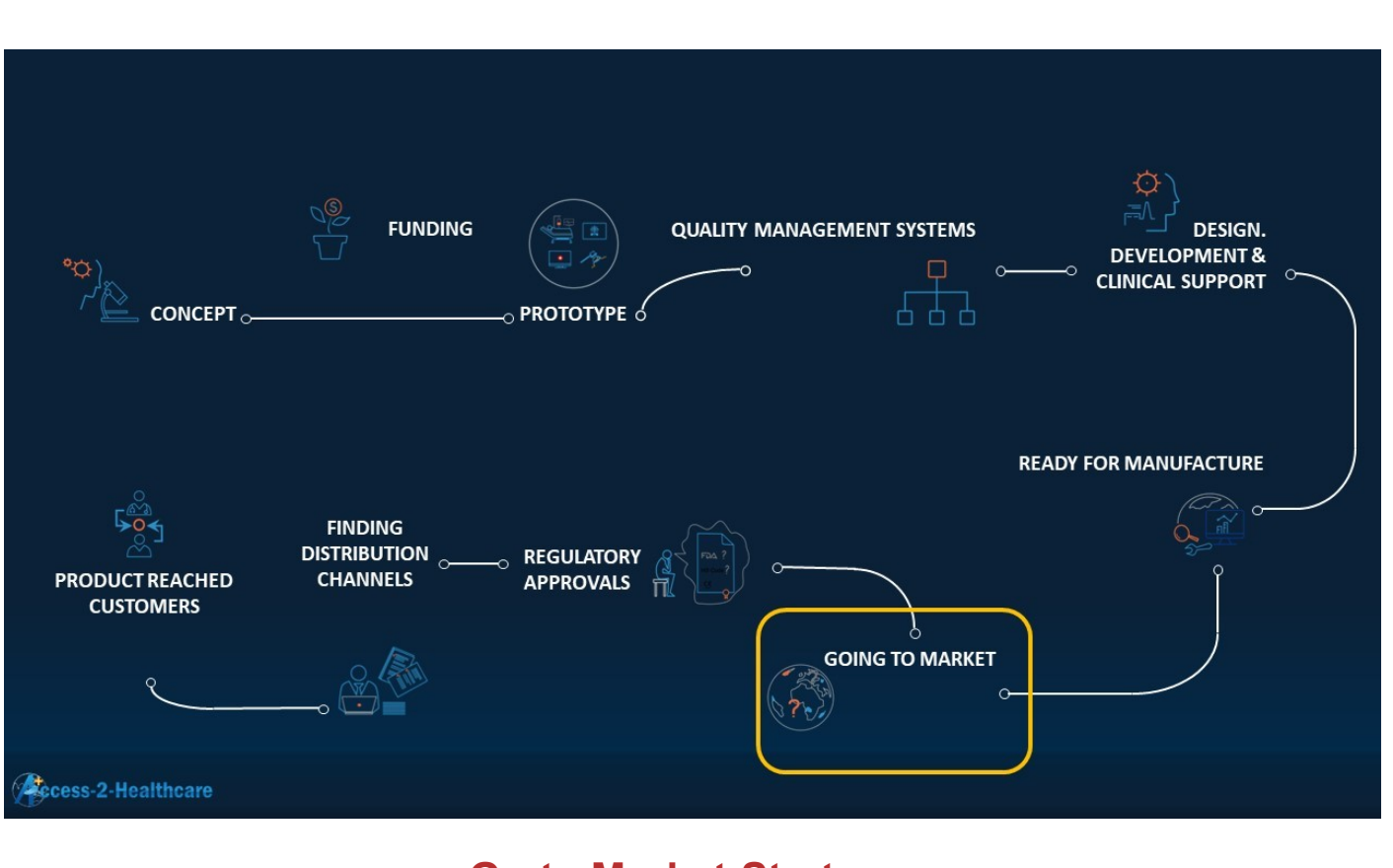


Go to Market Strategy
Leveraging Networks

A year ago, we were exploring the various different ways to establish a sales channel in a new market. One of them was to tag on another medical device's network and co-market.

Here we will discuss this in further detail, together with my recent findings from Arab Health 2023.

Digital Platforms and Software overlays (AI, CDSS) represent some of the most appropriate devices to be packaged together with the related hardware (sensor-based, monitoring based, diagnostic-based for digital platforms; hardware device needing annotation, guidance, diagnosis for software overlays).

This depends on:

- Which device was in the market first?
- Do they target slightly different market segments?
- Together, do they target a new market segment?
- They can be viewed as a total solution or a value-add.

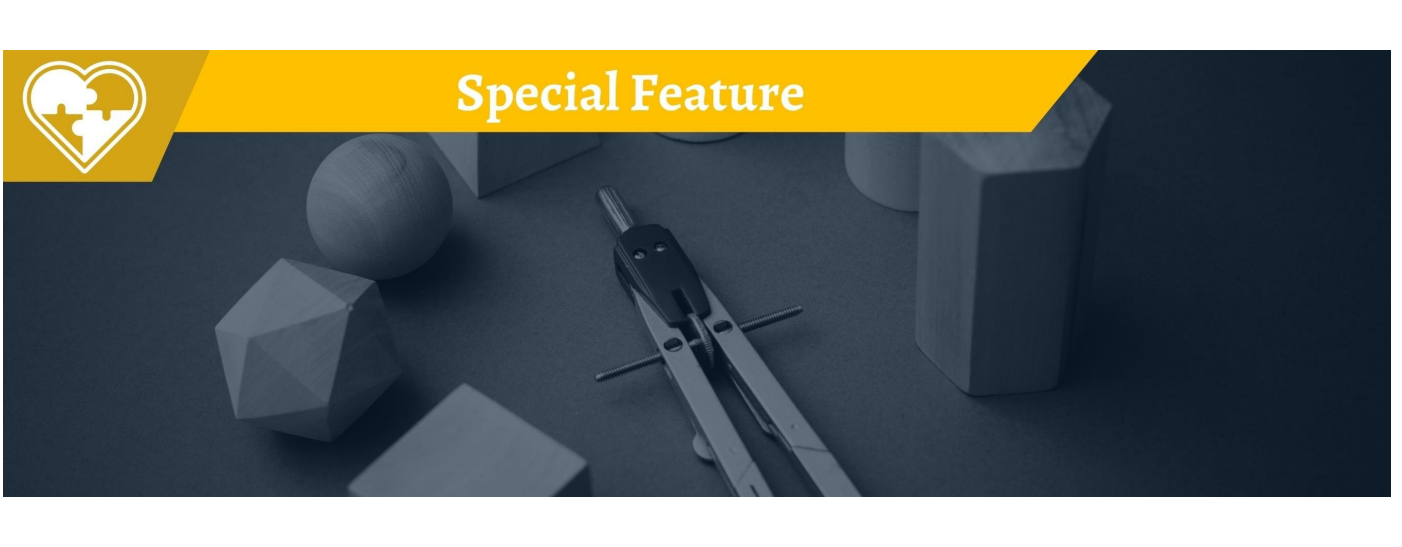
Complimentary devices to be sold as a system usually are targeted to be a total solution, to provide a comprehensive package for the end-user. Leverage on the existing sales channels, and then, it is greater than the sum of its parts when combined.

In general, the first steps are quite standard. Market access efforts are always needed, to build the brand and the channel first. Regulatory approvals are the next step.

Some other things to consider are whether the billing is done together with one of the device companies being the supplier. Another is the integration efforts required (network infrastructure, hardware upgrade on the hardware device, supply SDK, etc.) which are non-trivial.

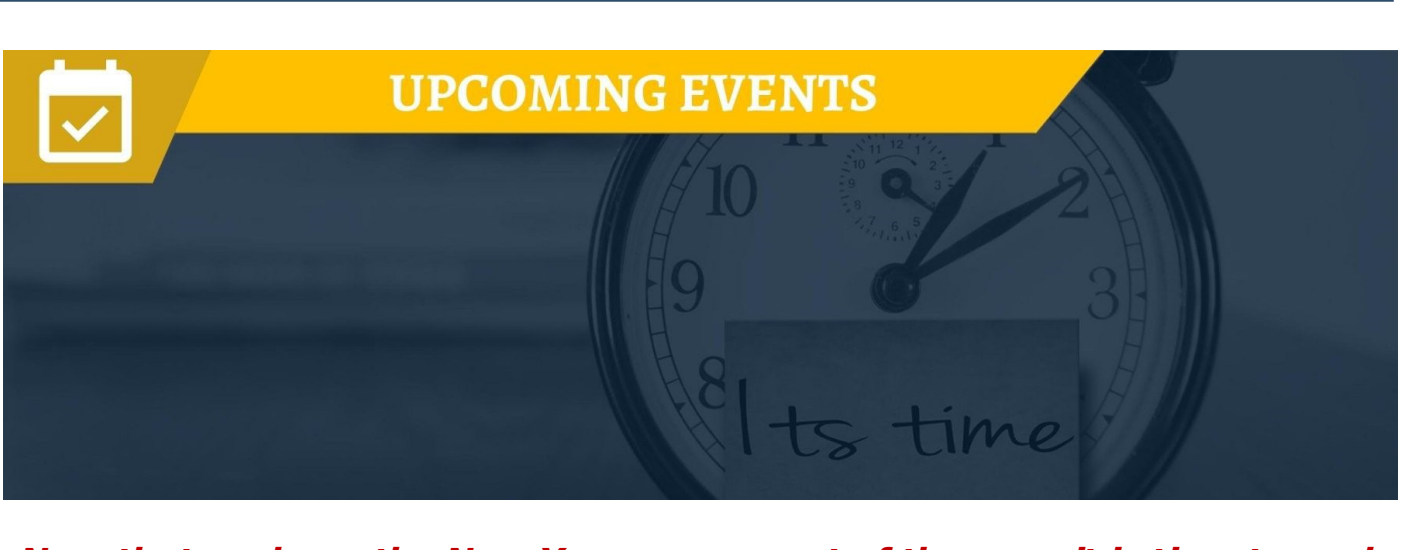
These suggestions mitigate the situation where your device represents a part of a total equation, or being in the middle-to-end pages of a distributor catalogue.

Any thoughts? We would love to know, so please write to us!



Arab Health 2023

Our Group Executive Director attended the Arab Health 2023 meeting that was held from January 30 to February 2 at the Dubai World Trade Centre. The meeting is also online for the first time in its history and will continue to run until March 2, 2021. Please check Access-2-Healthcare's Insight Blog for the report on this global event with around 3,000 companies and participants from 70 countries.



Now that we have the New Year season out of the way, it is time to pack your bags and head to some meetings. Here is a list to help you get

Ethio Health Exhibition and Congress 2023
February 23-25, 2023
Addis Ababa, Ethiopia

European Congress of Radiology
March 1-5, 2023
Vienna, Austria

International Eye Optics, Optometry and Ophthalmology Fair
March 3-5, 2023
Dubai, UAE

International Dental Show 2023
March 14-18, 2023
Cologne, Germany

Expomed Eurasia 2023
March 16-18, 2023
Istanbul, Turkey (Hybrid)

Medicall 2023
March 17-19, 2023
Hyderabad, India

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