

MEDTECH Gateway

Giving you the latest updates in the Medical Device Industry today

August 2022, Issue 44

Vacation?

August may be a summer holiday season for many, but [Access-2-Healthcare](#) is working hard to support you all year round. Take a look at this month's MedTech Gateway to stay up-to-date.



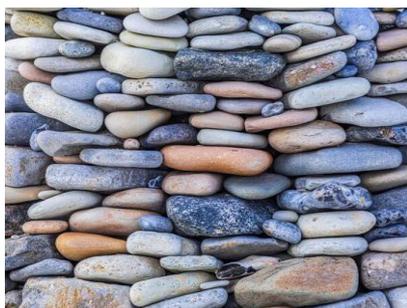
REGULATORY ROUNDUP

The latest regulatory updates for the medical devices industry



EUROPE

EU MDCG published its newest guidance on designation, re-assessment and notification of conformity assessment bodies and notified bodies on Aug 10, 2022. This guidance is intended to bring consistency and alignment in the working practices of different designating authorities.



Designation, re-assessment and notification of conformity assessment bodies and notified bodies

[Learn More](#)

AUSTRALIA

Australia TGA released an updated application form for priority applicant determination on Aug 2, 2022. To determine eligibility, applicants must complete the form and provide sufficient supporting documentation.



Application for priority applicant determination – medical devices

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INDIA



Application for priority applicant determination – medical devices

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On Aug 4, 2022, India CDSCO updated the list on classification of rehabilitation medical devices. 60 devices, ranging from Class A to Class C, were classified based on the intended use, associated risk and other parameters specified in the First Schedule.

VIETNAM

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Application for priority applicant determination – medical devices

[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 \[MA1\]](#)
4. [Berlin Cert Pruf \(Germany\) - 0633](#)
5. [CE Certiso \(Hungary\) – 2409](#)
6. [CENTRO NACIONAL DE CERTIFICATION \(Spain\) – 0318 \[MA2\]](#)
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. **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**
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IN-COUNTRY FOCUS

What are the latest in healthcare policies today?

US



HHS Invests Nearly \$60 Million to Strengthen Health Care Workforce and Improve Access to Care in Rural Communities

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced investments of nearly \$60 million to grow the health workforce and increase access to quality health care in rural communities, including nearly \$46 million in funding from President Biden's American Rescue Plan. The Biden-Harris Administration is committed to improving health outcomes and promoting health equity in rural America.

[Learn More](#)

KOREA



Korea Offers Training for Vaccine Production Personnel from Low and Middle Income Countries (LMICs)

Introductory Course for Biologics Development and Manufacturing' for vaccine production personnel from LMICs (117 trainees from 25 countries), as well as 33 domestic trainees, kicked off for its scheduled two-week course from July 18 (Mon.) to July 29 (Fri.) in Korea, the WHO-designated global training hub for biomanufacturing project.

[Learn More](#)

JAPAN



EISAI and LIFENET Enter into Capital and Business Alliance Agreement Aimed at Building Ecosystem to Reduce Burden of Medical and Nursing Care

Eisai Co., Ltd. and LIFENET INSURANCE COMPANY announced today that they have entered into a capital and business alliance agreement to collaborate in dementia and other areas, with the aim of helping reduce the burden of medical and nursing care for people living in Japan's aging society

[Learn More](#)

SINGAPORE



NHG and Tanoto Foundation Combat Diabetes with Diabetes Reversal Programme

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

SWITZERLAND



Smart Kidney Test Gets Green Light for Professional Use

The Swiss medtech company Bloom Diagnostics announced the launch of its newest product: the Bloom Kidney Test. The test is designed for the quantitative measurement of cystatin C in whole blood and to rapidly measure and quantify kidney function in users 18 years old and above.

[Learn More](#)

US

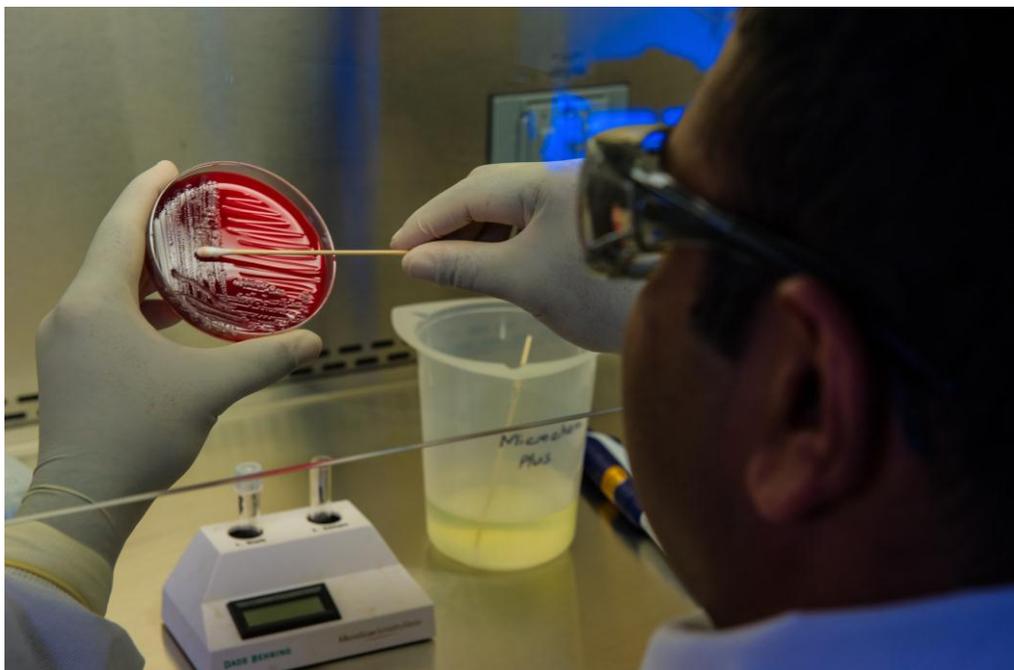


Aptar Pharma Acquires Orbital™ Dry Powder Inhaler (DPI) License

Aptar Pharma, a global leader in drug delivery and active material science solutions and services, announced that it has acquired the worldwide rights to clinical stage drug developer Pharmaxis' proprietary Orbital™ inhaler, a unique device designed to deliver high payload dry powder to the lungs.

[Learn More](#)

GERMANY

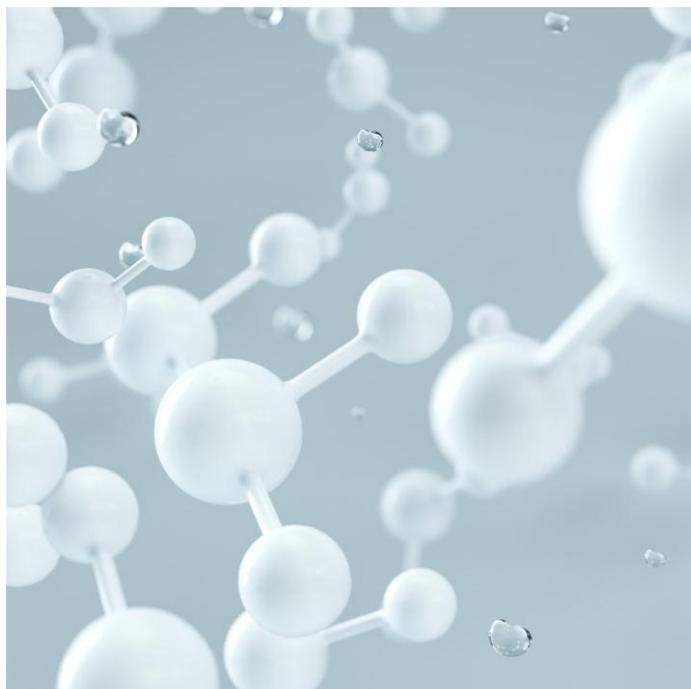


Sartorius to Acquire Albumedix, Strengthening its Portfolio of Innovative Advanced Therapy Solutions

The life science group Sartorius, through its French listed subgroup Sartorius Stedim Biotech, has agreed to acquire 100 percent of Albumedix Ltd. from private investors. The Nottingham, UK-based company provides best-in-class recombinant albumin-based solutions. Recombinant human albumin is an important component for the biopharmaceutical industry required for various applications, for example as an animal-free additive to cell culture media and for the stabilization of vaccines and viral therapies.

[Learn More](#)

AUSTRALIA



Griffith Launches Two Cancer Research Centres with \$4.6m ACRF Funding

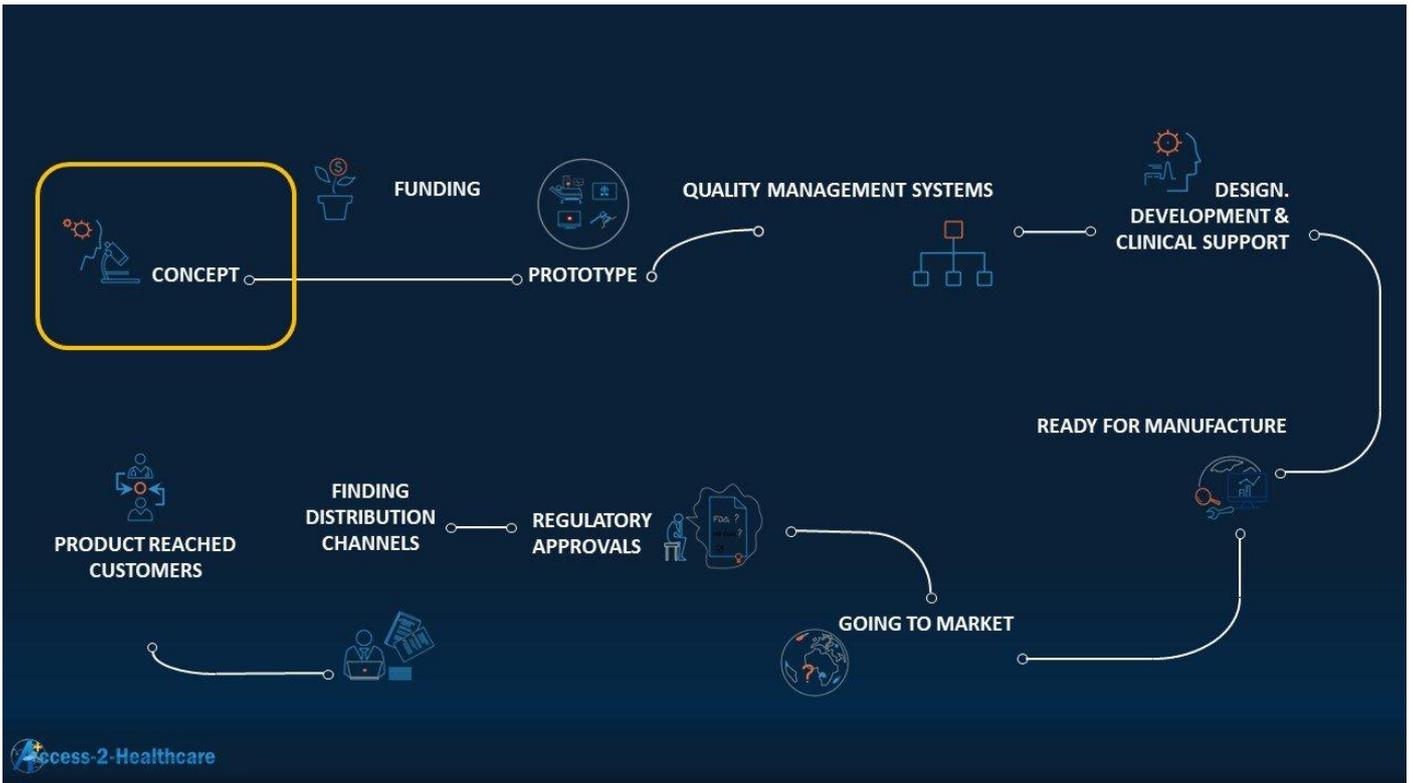
Griffith University has launched two cancer research centres backed by \$4.6 million in funding from the Australian Cancer Research Foundation (ACRF) this month. A \$2 million grant from the ACRF will fund a transformative compound management platform within the new ACRF Centre for Compound Management and Logistics at Compounds Australia – Australia’s only dedicated compound management facility.

[Learn More](#)



PRODUCT COMMERCIALISATION

Articles to help your journey in commercialisation.



Concept - Innovation from necessity



Not often a picture is included in our Product Commercialisation Series. But this is appropriate.

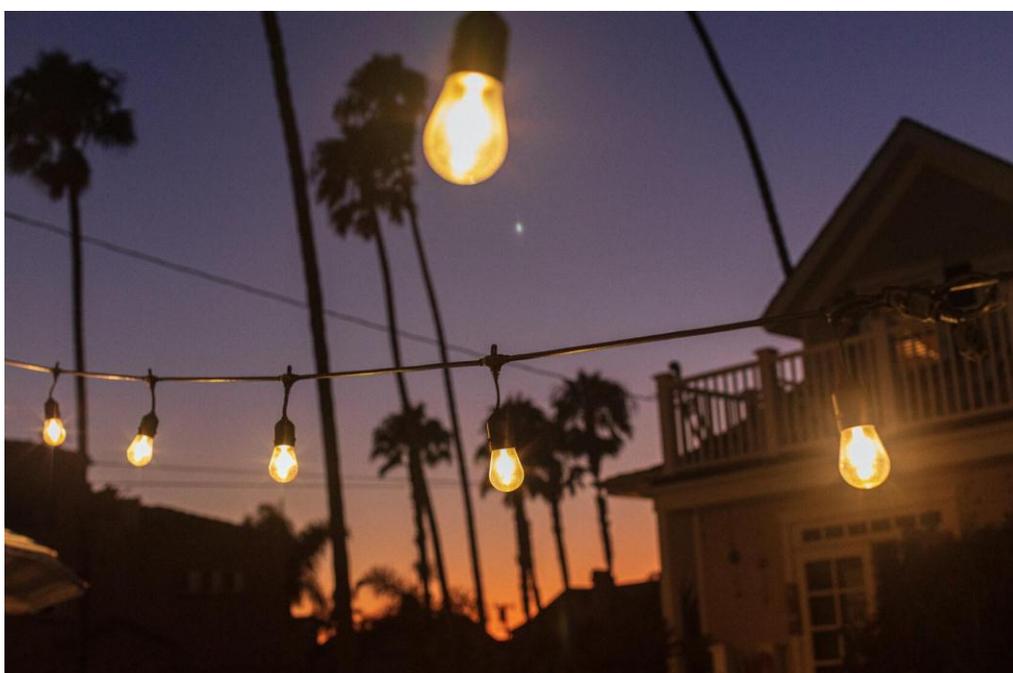
During an exploratory trip to understand healthcare ecosystems in various countries, I was on a bike in an island, as the pillion rider.

All it takes is the right-sized bottle (so that it fills up almost exactly a full tank of a bike), a funnel (see a bit of the red thing at the back, that's the funnel) to pour the petrol into the tank of the bike.

My friend said, "The petrol station is a few kilometres away. So this is a great service, because it saves me time and effort to ride there. Yes, they charge slightly higher, but it is just that little bit higher, and well spent especially for the time saved."

I have also posted it in [Post | Feed | LinkedIn](#) for everyone to take a guess, and people in the Asia region immediately knew what it was ☐.

Be at the right place at the right time, and provide what people need.



Summer Nights - Olivia Newton-John Cancer Research Institute

Known as a pop-singer and her major role in "Grease", Olivia Newton-John has also shared her battle with recurrent breast cancer for over 30 years and sadly lost the fight this month. Please take a moment to learn more about the Olivia Newton-John Cancer Research Institute, which will continue work in memory of their Founding Champion.

R.I.P. Olivia Newton-John

[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!***

[International Conference on Smart Medical Devices and Implants \(ICSMDI 2022\)](#)

August 16-17, 2022 Barcelona, Spain

[The 5th Edition of Medical Philippines 2022](#)

August 24-26, 2022 Manila, Philippines

[MEDICAL FAIR ASIA](#)

August 31 - September 2, 2022
MARINA BAY SANDS, Singapore
(Online: September 3-9, 2022)

[MEDTEC CHINA](#)

August 31 - September 2, 2022
Shanghai, China

[Medical Devices ASEAN \(MDA\) 2022](#)

September 8-10, 2022
Bangkok, Thailand

[RAPS CONVERGENCE](#)

September 11-13, Phoenix, AZ

[12th Annual Medical Device Strategic Pricing & Accounts Conference](#)

September 13-14, 2022
Chicago, IL

[Software Design for Medical Devices – Pharma IQ](#)

September 13-15, 2022
Berlin, Germany

The logo features a large blue letter 'A' with a white outline, set against a light blue globe. A blue arrow points from the bottom left of the 'A' towards the right. A yellow plus sign with a red pulse line is positioned at the top right of the 'A'.

Access-2-Healthcare



Our mailing address is: helpme@access2hc.com

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