

MedTech Gateway August 2020 - Issue 20

We are back after an absence of 7 months! This month issue continues to give you updates in the MedTech industry with a whole new layout!

[Access-2-healthcare](#)'s MEDTECH GATEWAY allows you to be closer in touch with the latest in the Medical Technology Markets, Regulations, Policies in Medical Device Market. Enjoy!

Regulatory Round-Up

AUSTRALIA

TGA Delays the Commencement of Medical Device Regulatory Changes

TGA delays which reflects the challenges identified by the medical devices industry and healthcare professionals to redirect their efforts to regulatory changes as they have focussed on the COVID-19 crisis.

[Learn More](#)

UNITED KINGDOM

MHRA- Medical Device "Certificate of Compliance" / "Attestation of Conformity"

The Medicines and Healthcare Products Regulatory Agency (MHRA) has warned that being issued certain certifications does not qualify a product to be marketed in the UK.

[Learn More](#)

UNITED KINGDOM

Medical devices: EU regulations for MDR and IVDR

The European Parliament and Council have approved a proposal to delay the full implementation of the MDR for one year to 26 May 2021, which means the full applicability of the MDR will fall outside of the transition period agreed with the EU.

[Learn More](#)

UNITED STATES

Artificial intelligence could improve accuracy, efficiency of CT screening for COVID-19 diagnosis

AI can improve CT screening for Covid-19 diagnosis. The new technique will reduce the burden on the radiologists tasked with screening each image, according to a research team from the University of Notre Dame.

[Learn More](#)

EU's Notified Body Tracker

Designated NBs

1. [BSI \(Netherlands\)](#) - 2797
2. [BSI \(UK\)](#) - 0086
3. [CE Certiso \(Hungary\)](#) - 2409
4. [DARE!!! Services \(Netherlands\)](#) - 1912
5. [DEKRA Certification \(Germany\)](#) - 0124
6. [DEKRA Certification \(Netherlands\)](#) - 0344
7. [DNV GL Presafe \(Norway\)](#) - 2460
8. [GMED \(France\)](#) - 0459
9. [IMQ \(Italy\)](#) - 0051
10. [Intertek IMNB \(Sweden\)](#) - 2862
11. [MDC Medical Device Certification \(Germany\)](#) - 0483
12. [MEDCERT \(Germany\)](#) - 0482
13. [NSAI \(Ireland\)](#) - 0050
14. [TÜV Rheinland LGA \(Germany\)](#) - 0197
15. [TÜV SÜD \(Germany\)](#) - 0123
16. [BSI Assurance UK Ltd](#) - 0086
17. [BSI Group The Netherlands B.V.](#) - 2797
18. [DEKRA Certification GmbH](#) - 0124
19. [TÜV SÜD Product Service GmbH Zertifizierstellen](#) - 0123
20. [DQS Medizinprodukte GmbH](#) - 0297

Recent Withdrawals

1. [DQS Polska](#) - 2282
2. [ECM Germany](#) - 0481
3. [LRQA](#) - 0088 QS
4. [Zurich](#) - 1254

In- Country Focus

TAIWAN

Seeing through Your Brain: High-End Biomedical Imaging Modality for Translational Research in Brain Mapping

In the multi-scale MRI system developed by NHRI researchers, the magnetic gradient of the human-size coil is approximately three times stronger than commercial clinical MRI systems.

[Learn More](#)

UNITED STATES

Helius Medical files application seeking FDA approval for device to help MS patients

Helius Medical Technologies has filed an application with the Food and Drug Administration seeking approval for the company's Portable Neuromodulation Stimulator (PoNS) device.

[Learn More](#)

UNITED STATES

TMC Identifying Molecular Targets to Prevent Obesity-Induced Cardiovascular Diseases

Obesity can have serious consequences of increased morbidity and mortality and may lead to many cardiovascular diseases. TMC has successfully developed tissue-specific transgenic models that can delete or over-express the epigenetic enzyme gene only in the endothelial cells

[Learn More](#)

UNITED STATES

CMS Proposes Updates to Coverage Policy for Artificial Hearts and Ventricular Assist Devices (VADs)

CMS seeks to ease rules on artificial heart, ventricular assist device coverage, responding to formal requests from device makers Abbott and SynCardia in 2019 to take a fresh look at reimbursement policies for the advanced heart failure technologies.

[Learn More](#)

Industry Insights

WishBone Medical Acquires 2 Firms to Expand Sterile Spine Product Range

WishBone Medical has acquired all assets of the privately held medical device companies Back 2 Basics Direct (B2B) and Orbbö Surgical.

[Learn More](#)

Abbott Announces Start of Study to Evaluate New Device to Treat Recurrent Atrial Fibrillation

Abbott has announced on TactiFlex PAF IDE study to evaluate a new device to treat people suffering from PAF, a type of irregular heartbeat.

[Learn More](#)

US: Radnet and Hologic partner on AI tools development for Breast Health

With this opportunity to leverage data from the largest fleet of high-resolution mammography systems to develop new tools across the continuum of care & improve patient satisfaction and outcomes

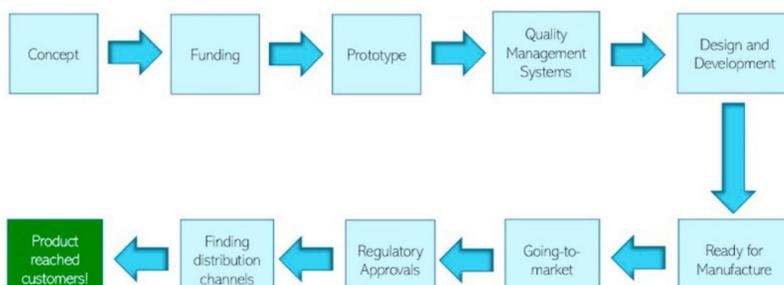
[Learn More](#)

Australia: Micro-X receives FDA clearance for mobile x-ray technology

Micro-X is pleased to announce it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for its 'Rover' mobile X-ray product which is designed for deployed military medical facilities.

[Learn More](#)

JOURNEY TO PRODUCT COMMERCIALISATION



We provide the perspective of each step in the Product Commercialisation process from our Group Executive Director, who had experienced every step of the way. When we reach the end, we will start again from the beginning, with a fresh perspective. **Enjoy!**

Planting your Success in Distribution

How do you distribute your product? Direct office? Distributors? A mix of both? And how do you manage them? Fly to meet them, calls, a bit of both, or not at all?

Distribution channels are like a plant: you have to nurture it- observe for positive and negative signs (business trends), maintain supply of nutrients (stock, product information), check for feedback, monitor conditions (the business environment), so the more attention and care you provide, the better it becomes. Some needs a lot of attention, some only a bit, because of various cultures, nature of business- just like different plants - needs different treatment.

It sounds simple yet, complex. Just like selecting a plant, right at the start of the product commercialisation process, you must understand the environment and the conditions, so as to match the appropriate distribution channel. Understand how much time you can allocate for each plant (channel partner, direct office), the amount of watering, pruning, re-potting (the effort placed on the distribution channel to meet, such as logistics, regulatory, product training, complaint handling) so that it is healthy, flowers, and/or bear fruit (sales KPIs, happy customers)

Perhaps Access-2-Healthcare is like your local gardener?

Special Feature



Focusing on medical device and technologies re not to be intended as drugs only. GCC MedTech able to provide a platform to discuss on how countries can best work towards harmonisation of medical device regulations in the GCC region.

MWAN Events and Access-2-Healthcare are happy to work together on this. Therefore, apply the discount code **Access-SEP20** to get a 20% discount on the registration fee.

Would You Like To Join Us?

As we are gradually expanding, we need talent like yourselves in our team to help the growth of the medical technology industry and to provide access to healthcare to everyone.

Contact to join us now!

[Mechanical Design Engineer \(Singapore\)](#)

[Regional Regulatory and Quality Manager \(Singapore\)](#)

[Supply Chain / Logistics Executive \(Part / Full time\) \(Indonesia\)](#)

[Supply Chain / Logistics Executive \(Part / Full time\) \(Philippines\)](#)

[Local Regulatory Expert \(Part Time\) \(Australia\)](#)

[Regulatory Affairs Manager \(Full time\) \(Indonesia\)](#)

[Outreach Manager \(On Call / Part Time\) \(Philippines\)](#)



We help medical technology companies with their product development, market launch and to gain market entry in various countries. Learn more about [us](#)

Access-2-Healthcare has been recently awarded as Best SME Medical Technology Consulting Solutions Provider - Asia Pacific, by Global Health & Pharma

[Learn More](#)



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