Summer is the time for fireworks!

July is the start of the second half of the year. Turn over a new leaf and start anew with this month's Access-2-Healthcare's MedTech Gateway for July 2022

EUROPE

The European Commission aims to have EUDAMED fully functional in the second quarter of 2024. The industry will have six or 24 months to comply to the obligations and requirements. The longer transition period applies to UDI/Device and NB & Certificate modules.

EUDAMED to be fully functional in Q2 2024

Learn more

MALAYSIA

Enforcement of Medical Devices (Establishment Responsibilities & Obligations) Regulations 2019

Learn more

MDA made an official announcement on the full enforcement of Medical Devices (Establishment Responsibilities & Obligations) Regulations 2019 with effect from Jul 1, 2022. All parties involved in the importation, distribution and placement of medical devices in the market are required to comply with all requirements set out in this Regulation, namely requirements related to complaint handling, field corrective action and recall.

AUSTRALIA

Advertising of all types of therapeutic goods must comply with Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021 and the Therapeutic Goods Act 1989 from Jul 1, 2022. Manufacturers and distributors can visit TGA's website to understand the applicable fundamental requirements.

Guidance on applying the Advertising Code rules

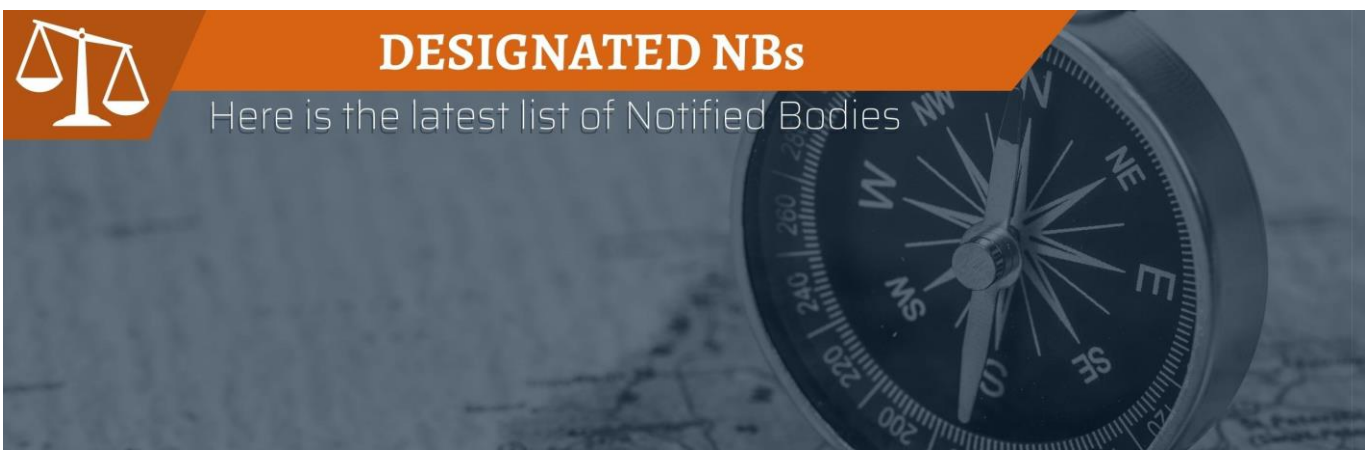
Learn more

CANADA

Proposed changes to the Medical Devices Directorate's (MDD) List of Recognized Standards

Learn more

Health Canada is proposing changes (addition, replacement, and removal of standards) to the Medical Devices Directorate's (MDD) List of Recognized Standards for medical devices. Industry stakeholders are welcome to contribute ideas and inputs by Aug 23, 2022.



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

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

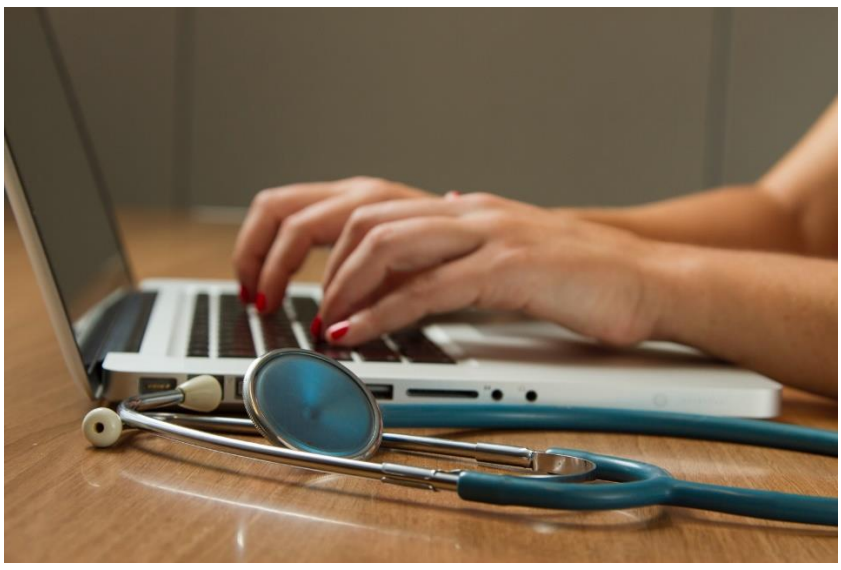
Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR):

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**

US



HHS Provides States with Additional Resources to Improve Oversight and Ensure Access to Quality Care in Medicaid and CHIP Managed Care Programs

Today, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS) unveiled a suite of new resources to improve CMS and state oversight of Medicaid and Children's Health Insurance Program (CHIP) managed care programs. These programs provide people with health benefits and additional services through contracted arrangements with managed care plans. Released in a Center for Medicaid and CHIP Services Informational Bulletin (CIB), this new information includes tools, templates, and updates on tactics to improve states reporting on their managed care programs, which promotes access to care for millions of people enrolled in Medicaid and CHIP.

Learn more

SINGAPORE

New Co-funding Scheme and Extension of Medisave Coverage to Support Eligible Couples in Their Parenthood Journey

The Ministry of Health (MOH) will introduce a new co-funding scheme and extend MediSave coverage for Pre-implantation Genetic Testing for Monogenic/Single Gene Defects (PGT-M) and Chromosomal Structural Rearrangements (PGT-SR) from 1 July 2022. These changes aim to provide financial support for eligible couples who would like to conceive but are at risk of transmitting serious inheritable diseases to their offspring, and are part of the Government's larger efforts to support couples in their parenthood plans.

Learn more

KOREA

Pilot Operation of the Sickness Benefits Program Launched

The Ministry of Health and Welfare (MOHW) announced that the pilot operation of the sickness benefits program, designed to guarantee income for injured and ill workers, will begin on July 4 (Mon) in six regions of Jongno-gu, Seoul; Bucheon, Gyeonggi-do; Cheonan, Chungcheongnam-do; Pohang, Gyeongsangbuk-do; Changwon, Gyeongsangnam-do; and Suncheon, Jeollanam-do.

Learn more

AUSTRALIA

Support for First Nations Elders to Access Aged Care

The Australian Government is investing $106 million to provide face-to-face support for older First Nations people and $115 million build culturally safe aged care facilities. This funding will be delivered over four years.
In an Australian first, the Trusted Indigenous Facilitators program will build a First Nations workforce to help individual older First Nations people, their families and carers, to access aged care services that meets their physical and cultural needs.

Learn more

UK

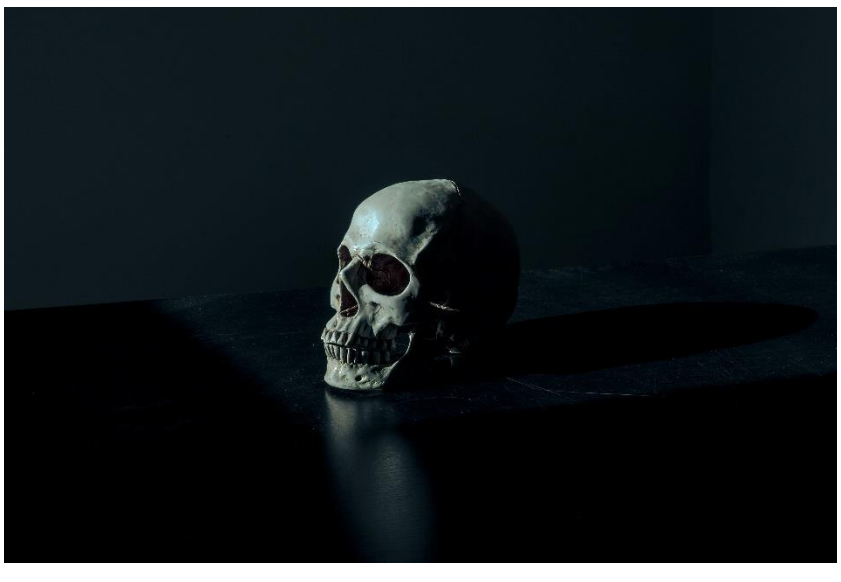
MCA launches digital Wellbeing at Sea Tool to support seafarer health and wellbeing

Poor mental health at sea is still taboo, and better support for seafarers must be embedded into the maritime industry, according to a new report funded jointly by the Department for Transport and the Maritime and Coastguard Agency (MCA).

The report comes alongside the launch of MCA's new digital tool designed to support seafarers' health and wellbeing. Called the Wellbeing at Sea Tool, the new website provides practical advice for seafarers and helps organisations monitor wellbeing and support their employees.

Learn more

BELGIUM



3D printed bone approved for patients in Europe

Surgeons in Europe now have access to MyBone, a patient specific 3D printed bone, to treat patients with severe facial deformations. This 3D printed bone is made of hydroxyapatite, a calcium phosphate which is the main mineral component of natural bone. MyBone is 3D printed with a unique porous structure by Cerhum, a medical device company in Liège, Belgium.

MyBone is the first commercially available 3D printed bone graft authorised under the Medical Device Regulation 2017/745 (MDR), registered with the Belgium Competent Authority (FAMHP, registration number BE/CA01/1-72228) and ISO 13485 certified.

Learn more

MALAYSIA

Smith+Nephew opens world-class manufacturing facility in Malaysia to support its orthopaedics business

Smith+Nephew, the global medical technology company, today opened its new high technology manufacturing facility in Batu Kawan Industrial Park in Penang, Malaysia. The 250,000 square-foot facility, worth more than USD100 million in investment, will primarily support the company's Orthopaedics business, which is expected to grow strongly in the Asia Pacific region.

Learn more

KOREA

Meridian Bioscience, Inc. Enters into Agreement to Be Acquired by SD Biosensor and SJL Partners in $1.53 Billion All-Cash Transaction

Meridian Bioscience, Inc. ("Meridian" or the "Company") (NASDAQ: VIVO), a leading global provider of diagnostic testing solutions and life science raw materials, and SD Biosensor, Inc. ("SDB") (KOSE: A137310) and SJL Partners LLC ("SJL") (collectively, the "Consortium") announced today that they have entered into a definitive merger agreement whereby a newly formed affiliate vehicle of the Consortium will acquire Meridian in an all-cash transaction valued at approximately $1.53 billion.

Learn more

SINGAPORE

MiRXES strengthens global fight against cancer with launch of world's first research project for a multi-cancer screening test using microRNA and multi-omics technology

A Singapore-headquartered biotechnology company, whose mission is to save and improve lives through early, actionable, and personalized diagnoses with its innovative RNA-powered cancer early detection solutions, announced today the signing of a Memorandum of Understanding (MOU) that launched Project CADENCE (CAncer Detected Early caN be CurEd). Project CADENCE is the world's first large-scale clinical research project for the discovery and validation of novel combinations blood-borne circulating microRNA (miRNA) and DNA methylation biomarkers that will lead to the development of a multi-cancer early detection test for up to nine high incidence and high mortality cancers, including lung, breast, colorectal, liver, stomach (gastric), esophageal, ovarian, pancreatic, and prostate cancers.

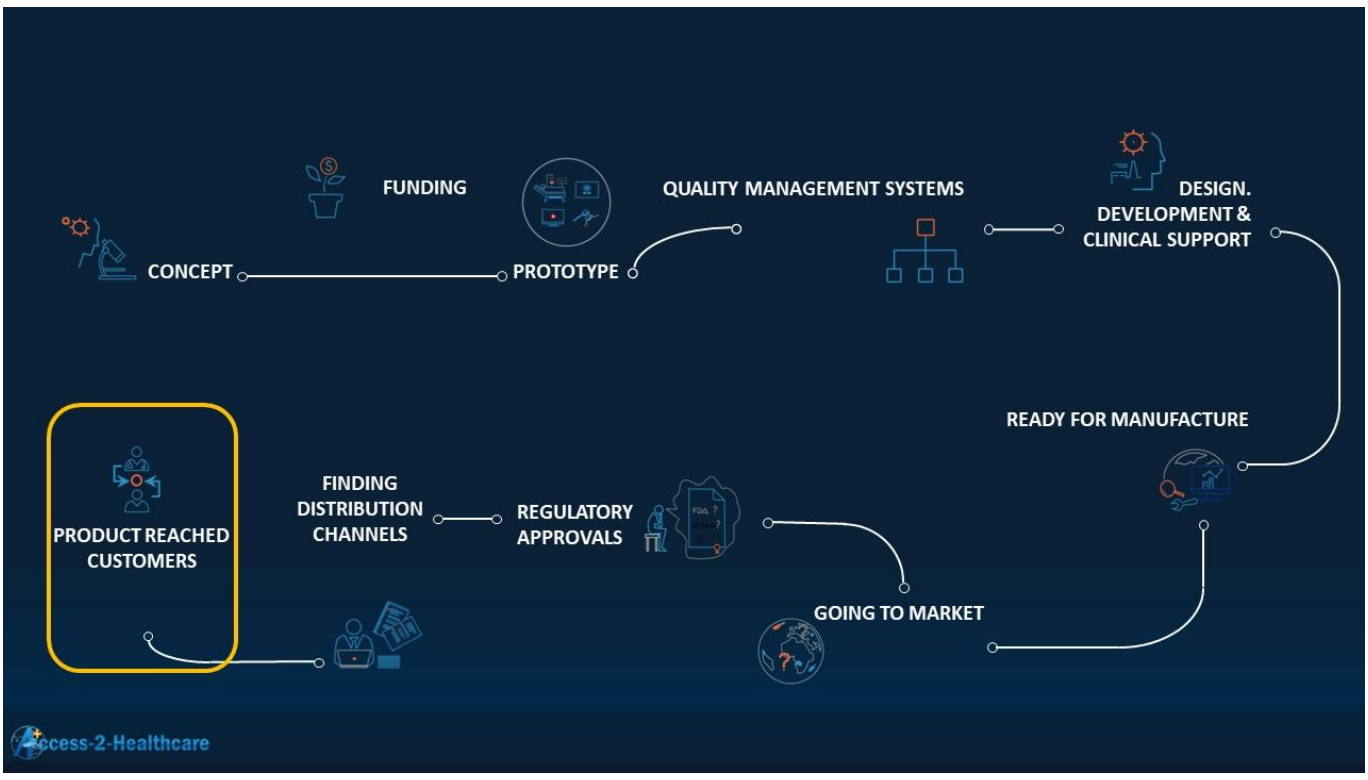
Learn more

FRANCE

Ganymed Robotics Raises €21M to Complete the Development of Its Next Generation Surgical Robot and Prepare for a Commercial Launch

Ganymed Robotics, a developer of computer vision software and robotics technologies for orthopedic surgeons, announced it has raised €21 million in the oversubscribed first close of its Series B funding. The round was led by Cathay Health, with participation of Credit Mutuel Innovation, Kurma Partners, BNP Paribas Développement and internationally renowned surgeons.

Learn more



Where the End is Actually the Beginning

End customers and post market surveillance
After the invoice is issued, money collected, is that all? Well, there would be after-sales service, either in the form of technical service, or just maintaining contact on the quality of consumables, or by the device's very nature, the customers must stay in contact (for example, remote monitoring). However. there are other reasons to keep in close contact with customers. Regulatory reasons.
Adverse events (AE)

It is a product defect which had occurred to your medical device, which leads to one of the following outcomes:

- It becomes a serious threat to public health.
- The death of a patient, user or other person.
- Serious deterioration in state of health of patient, user or other person.
- There is no death or serious injury in the initial AE but it might lead to death or serious injury of a patient, user or other person if the AE recurs.

There are cases where there is more than one device in which an adverse event had occurred, and/or is widespread. These are called Field Safety Corrective Actions (FSCA).

Product recalls

This is when the product can be brought back to your factory.

Product corrections

This is when the product cannot be brought back to the factory but can be repaired/corrected on site. It requires TRAINED service people, with the correct spare parts.

Labelling

This is when the problem has not reached critical point, may not be able to be recalled, and a customer communication or safety notice is issued to communicate to the customer about potential safety risks.

All regulated countries have a reporting scheme, process, and they all stress to report in a 'timely manner.' This is translated into a fixed number of days at maximum after the event has occurred.

With the IMDRF (https://www.imdrf.org/), and this process called NCAR (https://3c5.com/Uuvsd), other countries will know it too. Therefore, if it is indeed a systemic problem, and because it is a medical device, please do the responsible thing. Lastly, many regulated countries are gradually requesting for these information to be collected, trended and analysed. The distributors/importers/authorised representative needs to work closely with the factories to come up with it. As they are regulatory requirements, non-compliance usually would mean very bad things may happen to your business. So please comply 😊

Seize a chance to attend a medical device-related events and maybe even catch some fireworks as well

MEDITECH 2022
July 12-15, 2022
Bogota, Colombia

IMHS 2022 - International Modern Hospital Show
July 12-15, 2022
Tokyo, Japan

International Conference on Applications of Implantable Medical Devices (ICAIMD 2022)
July 19-20, 2022
Toronto, Canada

Florida International Medical Expo (FIME) 2022
July 27-29, 2022
Miami Beach, USA

Bio ASIA Taiwan Exhibition 2022
July 28-31, 2022
Taipei, Taiwan

Medicall – India\'s Largest Hospital Equipment Expo – 29th Edition
July 29-31, 2022
Chennai, India

Vietnam Medi-Pharm Expo 2022 (Ho Chi Minh)
August 11-13, 2022
Ho-Chi-Minh, Vietnam

8th Global Conference on Pharma Industry and Medical Devices (GCPIMD-2022)
August 13-14, 2022
New York, USA

Access-2-Healthcare