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European Regulatory Roundup January 2022: EU's Year Gets Off To Highly Productive Start

by Amanda Maxwell

January saw some key developments in terms of structures and documents to support the implementation of the Medical Device and IVD Regulations, including in the areas of Eudamed, the IVD Regulations, notified bodies and common specifications.

The Medical Device Regulation has applied since last May, and the IVD Regulation applies in less than four months' time, but many much-needed measures still need to be taken to support implementation. Nevertheless, January saw a bonanza of developments in many critical areas.

Not all the news is good though – notified body association TEAM-NB continued to warn of problems ahead. And many in the sector may be eyeing the increased involvement of the European Medicines Agency (EMA) in devices oversight with suspicion.

Indeed in January, the *EU officially adopted a new regulation making the agency involved in the management of two device functions*: the medical device expert panels, already established under the MDR and IVDR; and a new Executive Steering Group on Shortages of Medical Devices. *The regulation was published on 1 February*.

First Eudamed Certificate And IVDR Amending Regulation Published

The hot news at the end of the month was that the first certificate had been registered in the notified body modules of the Eudamed medical device database. It was entered by the Dutch notified body, DEKRA, on behalf of lung cancer diagnostics company Aidence BV. This is a quality management system certificate valid until 1 October 2025.

Eudamed is a key foundation of the new medical device regulatory system and is going to be *a major EU focus this year*.

This followed right after some other exciting medtech news - the *official publication towards the end of the month of the IVDR amending regulation*, which allows most IVDs more time to comply with the IVDR. The newly established staggered grace periods under the IVDR are risk-related so that the higher the risk the earlier the deadline for compliance.

EN ISO 13485 and 14971

The publication In January of the updated and harmonized version of the EN ISO 13485 quality system standard *in the context of both the Medical Device Regulation* and the *IVD Regulation* has been welcomed by the sector.

EN ISO 13485 is the most fundamental horizontal standard underpinning compliance with the new regulations. And in further good news according to the European Commission, the harmonized version of the updated risk management standard, EN ISO 14971:2019 with its amendment A11:2021, is likely to be officially published Official Journal of the EU in April. (The amendment, the commission says, has recently been made available.)

Other harmonized standards published in January included EN ISO 15223-1:2021, medical device symbols.

The Not So Good News

In January, a stark *warning was circulated by notified body association, TEAM-NB*, that the sector is heading for the untenable situation where the majority of valid certificates issued under the Medical Devices Directive will expire in the first five months of 2024.

It predicts “an extreme bottleneck in the processing of MDR/IVDR certification by notified bodies, which will increase towards 2024 proportionally to the amount to expiring directives’ certificates and will most probably prevent high numbers of devices currently certified under the directives from timely transition by 26 May 2024.”

As of September 2021, only 502 conformity assessment certificates had been granted by EU notified bodies in the context of the MDR and just 31 under the IVDR. Such small numbers barely scratch the surface in terms of starting to process the number of devices that will need to be certified under the new regulations.

More Notified Body News

Also in January, there were two new notified body designations under the MDR, *TÜV Nord Cert in Germany* and *Italcert* in Italy. This brought the total number to 27 under the MDR. And another two MDR designated notified bodies joined forces when *Norwegian notified body DNV acquired German competitor, Medcert,* in a move intended to address the peak in MDR certification demands.

At the end of January there were still only six notified bodies under the IVDR.

Annex XVI Breakthrough

Another key development during the first month of 2022 was the *publication of a draft implementing regulation for common specifications*, detailed technical requirements, for devices and substances used for aesthetic enhancement. These common specifications will effectively be mandatory for non-medical-purpose devices once the draft is adopted.

The draft foresees a staggered requirements to ensure full compliance with the common specifications when they become mandatory.

UK's Chief Regulator Joins BSI

Also, on the subject of notified bodies, it was announced that Graeme Tunbridge, head of devices at the UK's Medicines and Healthcare products Agency (MHRA) had joined BSI notified body after nearly two decades as a civil servant. He is succeeding Gary Slack, who will be retiring at the end of February after some 13 years at the organization.

Other News

In other popular news, the *rules on the labeling needs for medtech products entering the Swiss market* have been eased and industry association Swiss Medtech says the changes represent practical solutions that will forestall or reduce impending supply problems.

Furthermore, Elisabethann Wright, partner at Cooley law firm, explained *why scale of responsibilities for a virtual manufacturer under the EU MDR and IVDR* may deter many companies from taking on this role. Virtual manufacturers face increased requirements relating to technical file submissions, she said in an interview with Medtech Insight, as well as an obligation to fulfil post-market surveillance and vigilance activities and, where relevant, the need for notified body oversight. There are liability considerations too.

December And Annual Roundups

Two popular pieces in January summarized the European medtech regulatory news in *December 2021* and for *the whole of 2021, setting the scene for 2022*.

Below is the list of the top 10 most read EU regulatory pieces in January 2022:

Rank	Title
1	***Updated Version Of EN ISO 13485 Now Officially Harmonized Under MDR Along With Other Standards***

2	***European Regulatory Roundup 2021: Extensive Reshaping Of Underlying Medical Device And IVD Structures***
3	***European Parliament Gives Final Go Ahead To EMA's New Roles In Devices Oversight***
4	***EU Notified Bodies Warn Of Major Obstacles To MDR/IVDR Implementation***
5	***Two MDR-Designated European Notified Bodies Become One***
6	***Swiss Industry Makes Breakthrough For Local Market Device Labeling***
7	***Commission Publishes Draft Implementing Regulation For Insufficiently Regulated Products***
8	***MHRA's Graeme Tunbridge Joins BSI Notified Body***
9	***EU IVDR Amending Regulation Published And Staggered Grace Periods Now Official***
10	***Why Virtual Manufacturing Is Likely To Be Less Popular Under EU's New Device Regulations***