Lessons & Leftover Challenges from MDR Preparations: What Next?

A White Paper from Kallik

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As new device identification and traceability measures become compulsory in 2020, under the new EU Medical Device Regulation, we explore the residual issues that remain for manufacturers, especially with regard to global labelling management. How might they overcome these challenges effectively - so that they do not fall foul of the new requirements, and so that they are better prepared next time regulatory changes are brought in?

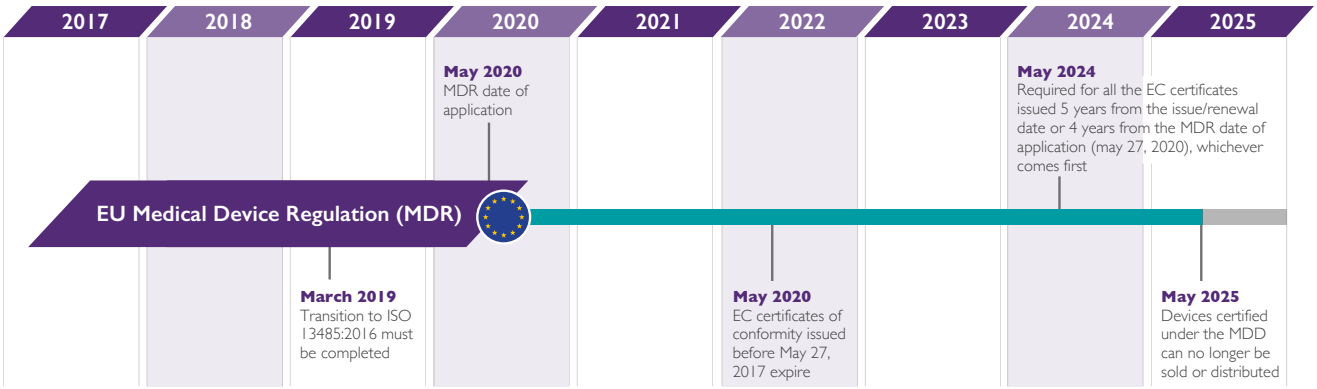
For the last couple of years, medical device manufacturers have been – or should have been – preoccupied with preparations for the EU's major revamp of the official safety controls governing medical devices sold and used across its jurisdiction. From May 2020, new medical devices coming onto the market must comply with the new EU Medical Device Regulation (MDR) requirements. Much has been written already about the phasing in of MDR, and the in vitro device equivalent, IVDR, and how requirements and timelines apply to different categories of device, but how well have manufacturers actually fared with all of this, and what challenges remain?

1. Starting from scratch: the pain of playing catch-up

The first hard lesson medical device manufacturers have had to get to grips with is just how demanding wholescale process change is, when regulators are the instigators and deadlines for compliance are immovable.

Up to now, compared to the adjacent pharmaceutical and biotech sectors, the medical device industry has got away with much more relaxed controls over device identification and traceability, and product lifecycle monitoring and reporting. This, added to the relative size and scale of many of the firms involved, has meant processes such as global labelling management have not been seen as a board-level priority.

Typically, physical labels are created as templates and printed manually on the factory floor using data from ERP systems, while other customer-facing materials such as instructions for use (IFU) leaflets tend to come under the remit of separate teams, even external design agencies in many cases. This disjointed approach does not lend itself well to the kinds of controls the EU is now imposing, which assume more systematic process coordination and content uniformity than that.



2. The centrality of labelling

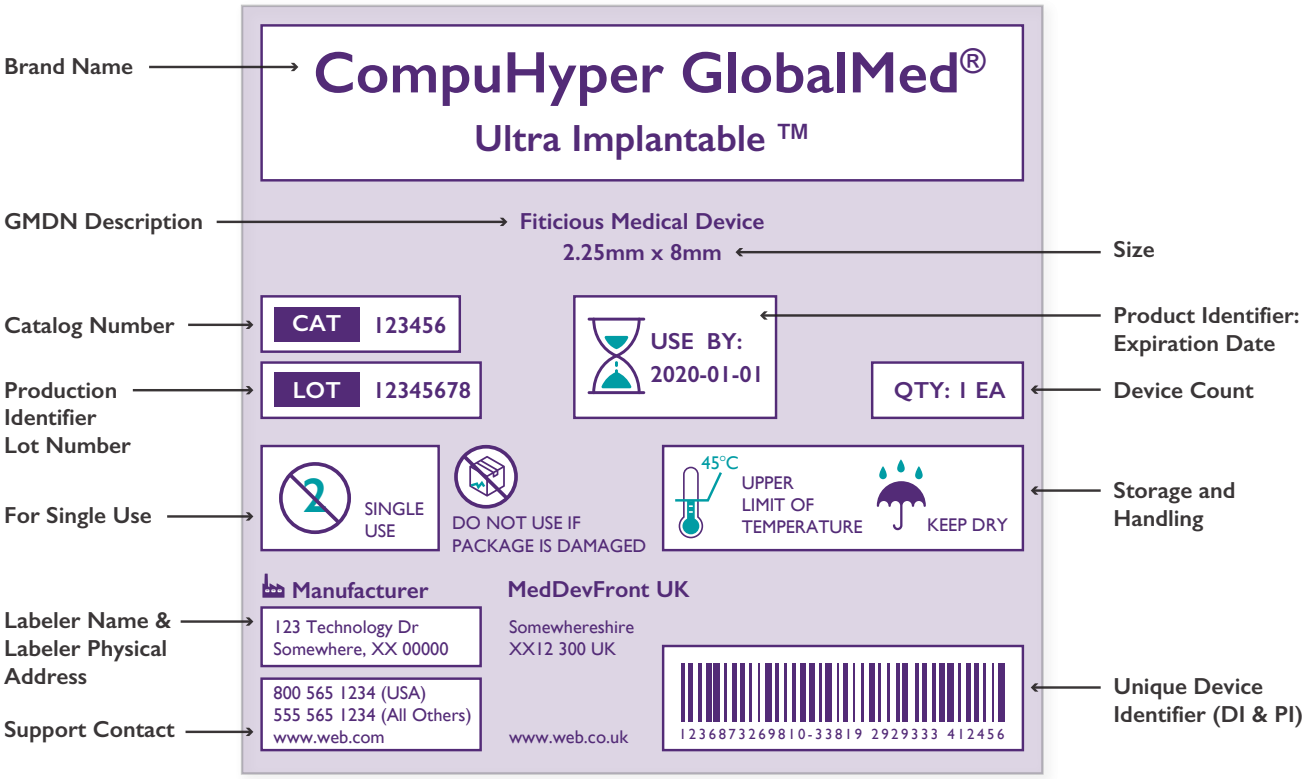
The stringent new measures under MDR/IVDR demand robust end-to-end product traceability, and that information is logged in a huge central EU database, EUDAMED – a prerequisite for marketing medical devices in European markets. This in turn requires that products are correctly labelled with specified safety information and symbols, and meet requirements around electronic IFUs. So, devising a more defined strategy for enterprise labelling and artwork is critical.

Device identification is a critical element in all of this. In the event of a safety scare and potential product recall, it is not enough for patients and their medical consultants or pharmacy outlets to know which type of device has been affected. To limit the damage, fear and hysteria, not to mention the cost to the manufacturer and the impact on their brand reputation, it is important that faulty batches of product can be pinpointed and tracked down in the market, for targeted remedial action. This in turn depends on accurate, consistently reliable labelling.

Under MDR, everything from bandages and crutches, to digital patient monitoring devices, contraceptive implants, hearing aids and pacemakers, will need to carry a unique device identifier (UDI) on all of its labelling, enabling rapid lookup in the event of an issue.

Any change to labelling can threaten the quality and reliability of what's issued, as even simple adjustments can throw out the layout, leave a barcode partially missing, or obscure critical wording. So, it is imperative that manufacturers aren't still relying on ad-hoc manual processes for ensuring that all ensuing output meets the new regulations consistently and definitively.

If the correct label is not fixed to the right product at the right time, products will not have the required transparency as they move from factories, through distribution, to the hospitals, doctors' surgeries and pharmacies who supply them, and the recipient patients. Incidents like the PIP breast implant scandal of 2009/2010, which triggered all of the new safety measures coming through now, could still wreak havoc. This is what MDR is designed to avoid.



3. Consolidated control & holistic visibility as critical success factors

Manufacturers cannot hope to keep on top of product identification and traceability, or manage this with rigour and efficiency, if they do not have clear visibility, control and systematic coordination across everything included on or with their products - through every channel, in every market.

In the final countdown to MDR compliance, there have been instances of manufacturers panicking that the internal systems they have created to handle the new requirements are not up to the task. Although the responsible teams at these companies know what they have to do, they have been unable to overcome concerns about getting the right labels out onto products and packaging – for instance, in scenarios where manufacturing and distribution operations span locations in the Far East and US as well as Europe itself.

It is finally dawning on these organisations that the only way to ensure consistency and reliability is to have a single source of labelling 'truth' that all market-facing product information and materials flow from; one definitive place to update and check everything - which any authorised team can access, anywhere in the world, supported by appropriate controls governing who can do what to and with the content assets.

4. Integrating & harmonising processes takes time

Probably the biggest impact MDR has had on medical device manufacturers relates to the scale of work involved. Many companies drastically underestimated this, leaving projects too late. Dispersed teams and disjointed processes, as well as inevitable duplication between content sources such as translation databases (for instance where these have existed separately for label and IFU creation), make for highly complex scenarios that take time to unravel. That's before improvements can be implemented to streamline and (where possible) automate processes, such as change management.

The danger where companies have left MDR preparations until the eleventh hour is that they are forced by time pressures to do the minimum required for compliance, even if that is a costly workaround that doesn't deliver the quality control, compliance confidence or process efficiencies the manufacturer needs.

5. Change is a constant

Another hard lesson is that regulatory disruptions are not a one-off event; or certainly they won't be from now on. MDR will not be the only major global change to come the industry's way, so companies that haven't taken the time to do things properly this time around are likely to have to do it all again next time new requirements are introduced – for example product serialisation on device labelling is likely to become mandatory in the coming years.

For the time being, manufacturers marketing products in Europe only have to provide UDI information to the EUDAMED database, but starting from May 2021 unique product identifier codes/detailed product serialisation information will have to appear on all product labelling. The 2021 deadline applies for the most safety-sensitive - Class III - devices; followed by Class II in 2023, then Class I items in May 2025. The UDI must appear in plain text on all packaging parts of a product; be machine-readable; and include a wealth of very specific information under two different categories – a Device Identifier (DI) and a Production Identifier (PI) – so there is a lot to get right in the coming months and years.

This is the first time in the medical device sector that changes to labels and IFUs have come at the same time, driving home to manufacturers just how inadequate some of their existing disconnected processes are. If they haven't already, companies are likely to review the extent of their inefficiencies and start working towards a common approach to managing market-facing information, based on common content and shared data, and more joined-up ways of working.

While the tasks that still remain may sound onerous, it is worth companies keeping in mind the bigger picture in all of this, which is about ensuring patient safety and restoring public trust in the industry and its products. Those manufacturers that are seen to comply readily, even going the extra mile to give consumers the reassurances they need, will gain in market confidence around their brand. The desire for greater transparency, and consumer self-service (the ability to look up the products prescribed to them), is not going to go away so the more than manufacturers can do proactively to satisfy this need, the better received their products will be. The specific requirements of MDR are just part of this bigger picture, so manufacturers should not be limited by them.