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Supporting your needs

May's drop dead date for the Medical Devices Regulation doesn't affect me. Is that right?

The Medical Devices Regulation (MDR), which comes into effect this May, places responsibilities on anyone working in any way with Medical Devices, and this includes dealers (and others) who are included under the MDR definition of 'Distributors'. Preparing for, and Interpreting the MDR has been taxing many businesses over recent years and months – if you haven't started, get going quickly since the clock's ticking down fast. This article picks out some of the elements of relevance to THIIS readers.

Since 1994, we have been living under the Medical Devices Directive for medical CE marking. From 26 May 2020, its replacement, the EU Regulation on Medical Devices (Regulation EU 2017/745)1 (MDR), takes full effect. Whom does this affect, and in what way? This article attempts to summarise some of the impact that moving under the MDR will be having on consumers, dealers, importers, and manufacturers.

The impact of some textured silicone filled breast implants leading to the deaths of a number of women triggered the call for the Medical Devices Directory (MDD) to be updated, and ended up with its being replaced by the Medical Devices Regulation (MDR).

The MDR was published on 7 April 2017, and we had three years to implement it, to 26 May 2020. (Note: up to May 2024 MDD certificates of conformity dated before 26 May will remain valid until their expiry date.) Three years have been needed, since the demands on manufacturers and their customers have escalated as the data they have to produce and record has multiplied many times. In the UK, we still have to follow the EU rules until at least the end of 2020, and will need to do so if selling into the EU thereafter, and very possibly in the UK as well (possible replacement legislation is under review at present).

What is a Medical Device?

The MDR covers only medical devices. What is a medical device is defined in the MDR (see Figure 1). Medical devices have to be labelled as such under the MDR. But note that the new definition means that some products, such as commodes, which previously may have been medically CE marked, will no longer be eligible to be described as such from 26 May, if they do not fall under

Figure 1. Definition of a Medical Device in the MDR

'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- Devices for the control or support of conception
- Products specifically intended for the cleaning, disinfection or sterilisation of medical devices as referred to in Article 1 (4) and of those referred to in the first paragraph of this point

How does a medical CE Mark differ from another CE Mark?

If your product has a CE mark on it, currently there has been no indication on the device whether that product has that mark under the medical regulations, the electrical regulations, the toy regulations, or any other of the EU applicable regulations. The MDR now requires that a medical device has a label on it saying that it is a medical device – and within EU regulations this label has to say this in each language of the EU where the device is made available. However, instead of writing this in 24 languages, the proposed revision of ISO 15223-1 offers a symbol which can be used instead:

Dealers are 'Distributors'

Figure 2: MDR Article 2.34 Definitions

'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service

Under the MDR definitions (Fig. 2), dealers, for example, are classified as Distributors, and thus have new obligations to be met: e.g. Article 14 (General Obligations of Distributors), which states: "Before making a device available on the market, distributors shall verify that all of the following requirements are met:

a) The device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

b) The device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10 (11);

c) For imported devices the importer has complied with the requirements set out in Article 13 (3)

d) That, where applicable, a UDI has been assigned by the manufacturer"

Medical Device Classification under the MDR

Classifications within the MDR are clearly spelled out: however, this does mean that some medical devices which had been classified as Class I under the MDD may now be considered to be Class IIa, depending on the claims made for the device.

One new aspect has been the inclusion of devices that clean, disinfect, or sterilise medical devices, which are now classified as medical devices: equipment which disinfects is classified as IIa at a minimum. Items which transfer energy into the body (such as electrical position changers in beds, leg elevators on wheelchairs, etc) are IIa (and were under the MDD). Items which come into contact with open wounds are IIa – this could affect the classification of a number of cushions, mattresses, etc. Again, the classification level goes back to what the manufacturer makes claims for, for his device.

Track and Trace

MDR Annex VI is devoted to the requirements for providing Unique Device Identifiers (UDIs) for each medical device so that medical devices can be tracked and traced in case of the need for a recall, or tracing where defective devices may have been used. Within GS1 coding the UDIs are the Global Trade Identification Numbers (GTINs) – these are the barcodes you see on most items in the retail trade, from a can of Coke, to your phone. Alongside the GTIN, in the UK the NHS now requires a batch or serial number, the date of manufacture, and, if appropriate, a use-by date, as a minimum. These items are best encapsulated into an EAN128 2D datamatrix code. For more details on barcoding, refer to the BHTA guidance document downloadable from the BHTA website2.

The MDR is a large document aimed at all medical devices, and attempts to cover all possibilities. This article has concentrated on some of the elements relevant to THIIS readers. However, the breadth of coverage of the MDR means that in places there are areas that are open to interpretation. An observation made to me by someone from the MHRA is that clarification may not become apparent until some trial cases have been taken through the Courts!

References

1.The MDR can be downloaded from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745

2. The BHTA barcoding guidance document can be downloaded from the BHTA website: http://www.bhta.com/gs1/ and http://bhta.com/wp-content/uploads/2018/04/BHTA-Barcoding-2014.pdf

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