



Medicines & Healthcare products  
Regulatory Agency



# Virtual manufacturing of medical devices

**Version 2.0**

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V1.0	March 2017	n/a
V2.0	April 2019	Section 1 – updated Section 2 - updated Section 3 – updated Section 4 – updated Section 5 – updated Section 7 – new section added Section 8 –used to be section 7. email updated Section 9 – added to cover distribution

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## 1. Overview

This document supersedes the previous edition of the guidance, 'Virtual manufacturing replaces own brand labelling for medical device manufacturers' dated March 2017 which replaced previous MHRA guidance on 'Own Brand Labelling' (OBL).

The European Commission's Recommendation 2013/473/EU published in October 2013 significantly amended the expectation for manufacturers who do not design or manufacture devices but place their names as the manufacturer on to devices designed and manufactured by another party. This party is generally referred to as the original equipment manufacturer (OEM).

It should be noted that this document applies to manufacturers in conformity with the Medical Devices Directive (93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (98/79/EC) as well as the new Medical Device Regulations (2017/745) and In Vitro Diagnostic Medical Device Regulations (2017/746).

## 2. What has changed?

MHRA replaced the term 'own brand labelling' with 'virtual manufacturing' in March 2017.

Previously the UK accepted summary technical documentation (STED) to be held and reviewed by notified bodies.

Now all virtual manufacturers must hold the **full technical documentation** for any product they place on the market under their name.

## 3. What is a virtual manufacturer?

A virtual manufacturer is an organisation that fully sources its own named product from another company (sometimes known as the 'original equipment manufacturer'), which has designed and manufactured an identical CE marked product. By placing their own name and address on the product, the virtual manufacturer takes on the legal responsibilities for the medical device and is therefore regarded as the manufacturer in accordance with the medical device regulations.

Note that in practice there is no difference in the regulatory requirements applying to a manufacturer and a virtual manufacturer.

## 4. Responsibilities of a virtual manufacturer

Where notified body certification is required, the virtual manufacturer must have a quality management system that will be audited by their notified body. In addition, virtual manufacturers are expected to hold the full technical documentation which may be reviewed by a notified body. Virtual manufacturers of medical devices that don't need notified body approval are still required to hold the full technical documentation for their medical devices, which may be examined by the competent authority. Virtual manufacturers, where relevant, are also required to meet the registration requirements (e.g. for Class I devices, IVDs etc.).

[Annex II of Recommendation 2013/473/EU](#) states:

"Notified bodies should note that manufacturers:

- (a) have to fulfil their obligations themselves regardless of any partial or total outsourcing of the production via subcontractors or suppliers;
- (b) do not fulfil their obligation to have at their disposal the full technical documentation and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system;
- (c) should integrate the quality system of critical subcontractors and of crucial suppliers with their quality system;
- (d) need to control the quality of services provided and of components supplied and the quality of production thereof regardless of the length of the contractual chain between the manufacturer and the subcontractor or supplier”.

Under the medical device legislation, the virtual manufacturer is also required to sign a Declaration of Conformity that the devices concerned meet the requirements of the Medical Devices Directives.

*Note: All virtual manufacturers, including those manufacturing Class I medical devices, are required to comply with the revised requirements.*

## **5. What technical documentation does a virtual manufacturer need?**

All manufacturers are expected to hold full technical documentation in order to demonstrate that the medical device that they place on the market, under their own name, meets the regulatory requirements.

The existing Medical Devices Directives are currently applicable and detailed guidance has been issued on the content of technical documentation in [NB-MED/2.5.1/Rec.](#)

In addition, Annex II of the [Medical Device Regulations \(2017/745\)](#) and [In Vitro Diagnostic Medical Device Regulations \(2017/746\)](#) provide detailed information regarding expectations for technical documentation.

The technical documentation should be fully integrated into the manufacturer’s quality management system where applicable and should contain data relevant to the manufacturer (e.g. labels, instructions for use, risk assessment etc.)

Where the virtual manufacturer does not hold the rights related to product design, the notified body and competent authorities may accept a technical file from the virtual manufacturer that has redacted proprietary information as long as the redacted information is not essential for the purposes of the notified body or competent authorities assessing whether the medical device complies with the regulatory requirements. Redactions should be as limited as possible.

In cases where the virtual manufacturer holds redacted technical documentation, they must have contractual arrangements to ensure full disclosure of all applicable information by the original equipment manufacturer (OEM) directly to the notified body of the virtual manufacturer (without the further need for agreements to be put in place between the notified body and the third-party OEM).

The following may constitute proprietary information:

- a. unique material formulae or ingredients which are specific to the medical device and not in general use which are of high commercial and intellectual benefit to the OEM

- b. unique manufacturing processes which have been designed by the OEM and give them a competitive advantage in the market place
- c. technical drawings and technologies (applicable where a patent is also being applied for) but not yet granted
- d. software algorithms

*Note: Full redaction of all formulas, ingredients, algorithms or manufacturing processes cannot be accepted. Where redactions are made, the justification for these redactions by the OEM must be documented and the top-level information provided should be sufficient to understand the medical device and any associated risks.*

Any technical documentation provided to a notified body should include a statement drawn up by the virtual manufacturer indicating they fully understand all the documentation provided and that they accept full legal responsibility.

## **6. What should the contractual agreement between both parties cover as a minimum?**

Virtual manufacturers will need to ensure an appropriate contract is in place with the OEM. As a minimum, the contractual agreement should contain the following:

- a. A direct link between the medical devices being placed on the market by the manufacturer that holds the rights to the product design and the virtual manufacturer they are supplying who does not hold the design rights (e.g. by name / part number).
- b. Arrangements for post-market surveillance and vigilance activities (i.e. details of who is responsible for what in relation to these requirements, including reporting of adverse incidents). All virtual manufacturers should ensure that incidents or potential incidents are reported and also brought to the attention of the manufacturer that holds the rights to the product design. Similarly, the manufacturer is responsible for notifying the virtual manufacturer to enable them to take appropriate action with regard to their own products.
- c. Provisions for post-production follow-up, including ensuring that post-market clinical follow-up provisions are in place.
- d. Arrangements for details of any changes to the medical devices to be notified to both parties, with documented approval granted by the OEM where the virtual manufacturer wish to make changes.
- e. Provisions for unannounced audits – i.e. the notified body of the virtual manufacturer will be required to have access to any critical suppliers (including the manufacturer who holds the rights to the design).
- f. The contract should include the fact that the virtual manufacturer may not enter into another contract with another virtual manufacturer for the same device, i.e. a virtual manufacturer cannot be the OEM for another virtual manufacturer for the same medical device.
- g. Provision for the OEM (including the manufacturer who holds the rights to the design) to provide fully un-redacted information upon request of the notified body of the virtual manufacturer, without the requirement for further contractual actions between the notified body and critical supplier such as non-disclosure agreements.
- h. Provision for the OEM, where relevant, to maintain and provide to the virtual manufacturer notified body certification covering the products concerned.

- i. Provision for the OEM, where relevant, to maintain and provide to the virtual manufacturer evidence of registration (e.g. for their Class I devices, IVDs etc.) with their competent authority.

## **7. What options does a virtual manufacturer have if their OEM loses their CE certificate?**

- a. obtain evidence of the suspension/withdrawal of the certificate
- b. consider whether there is a safety concern and any impact on the virtual manufacturer's own certificate and products on the market
- c. understand what arrangement (if any) the OEM is under with their local competent authority
- d. consider using the OEM as a critical supplier to allow continued supply of the virtual manufacturer's product
- e. inform your notified body immediately of the loss of the OEM's certificate

## **8. How should disputes with UK notified bodies be handled?**

If there is a dispute between a UK notified body and a virtual manufacturer regarding the regulatory requirements, contact MHRA for clarification by email:

[devices.regulatory@mhra.gov.uk](mailto:devices.regulatory@mhra.gov.uk).

## **9. If a virtual manufacturer wants to change from being the legal manufacturer to the distributor**

A virtual manufacturer will be considered a distributor and not the manufacturer in the following situations where they:

- a. provide a translation of the information supplied by the manufacturer for the purpose of making the product available in a different EU member state (without affecting the integrity and detail of the information provided by the manufacturer). The manufacturer must have a process to verify that all translations are fit for purpose prior to authorisation
- b. change the size and/or presentation of the outer packaging of a device that has already been placed on the market without affecting the integrity of the device itself
- c. affix their brand name or trademark on the labelling with the agreement of the manufacturer and the manufacturer is identified on the labelling and packaging
- d. stipulate clearly who the device is 'distributed by' and 'manufactured by' on the packaging and labelling
- e. do not change the intended purpose of the device or modify the device or its packaging in such a way that its compliance with the legislation is affected.

In order to be considered as the distributor there would need to be signed agreement with the manufacturer. The manufacturer's name must be visible as the legal manufacturer on the packaging and labelling. These details should be easy to read. There is the option for the distributor to be identified on the packaging and labelling with the term 'distributed by'.