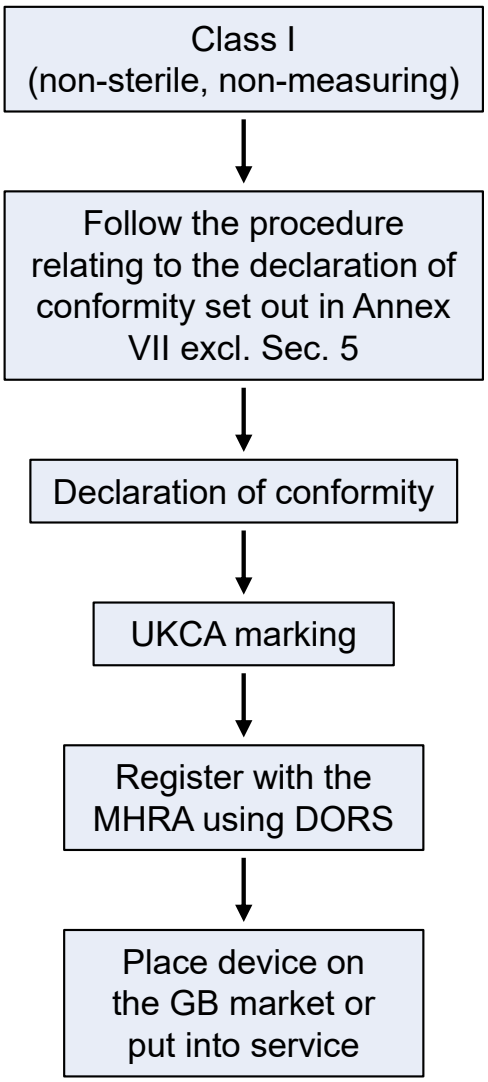
Medicines & Healthcare products Regulatory Agency

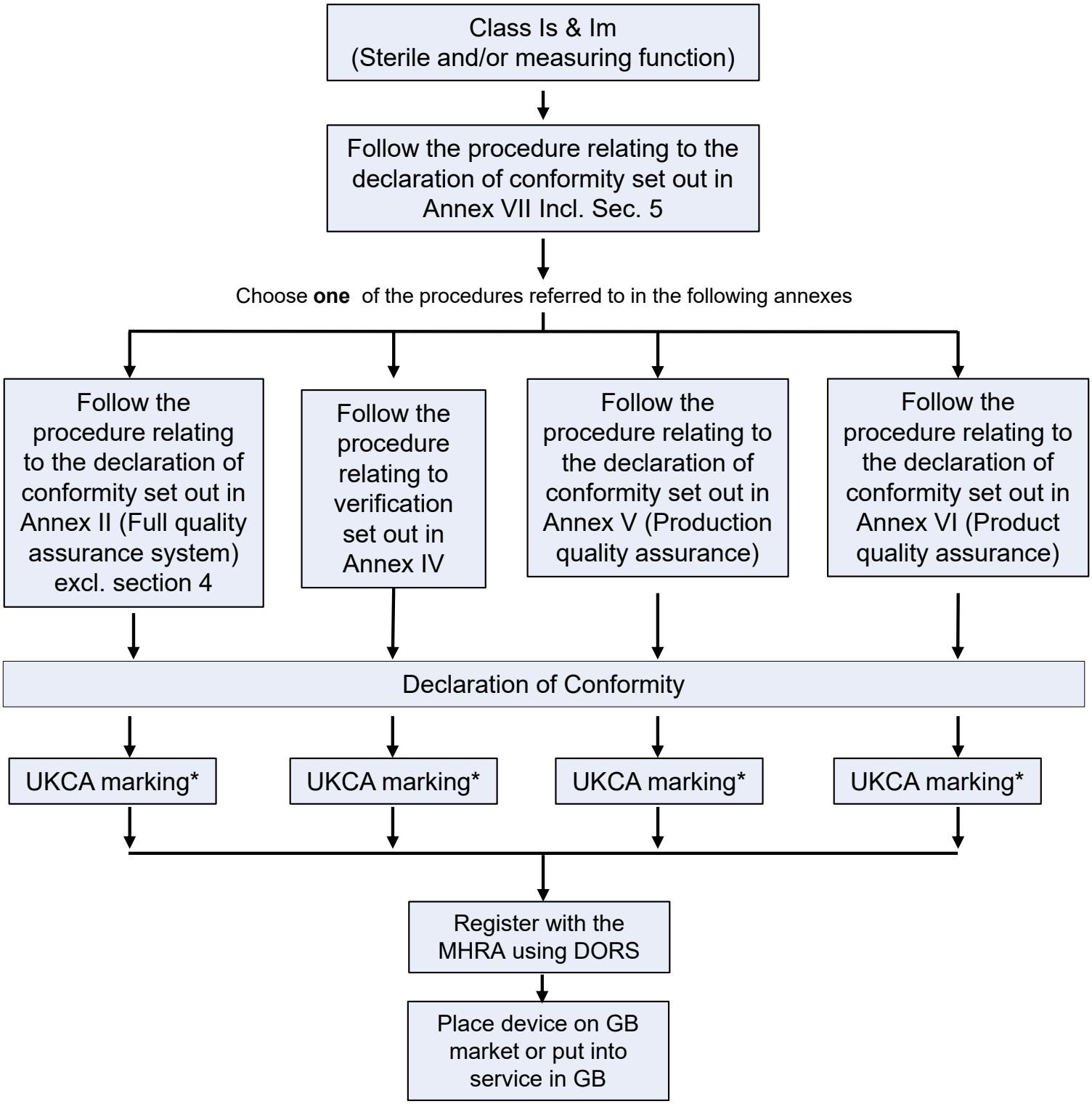
UK MDR 2002 (SI 618, as amended) Class I Conformity Assessment Routes (non-sterile, non-measuring)



No involvement of an Approved Body

Medicines & Healthcare products Regulatory Agency

UK MDR 2002 (SI 618, as amended) Class I Conformity Assessment Routes (sterile and/or measuring function)



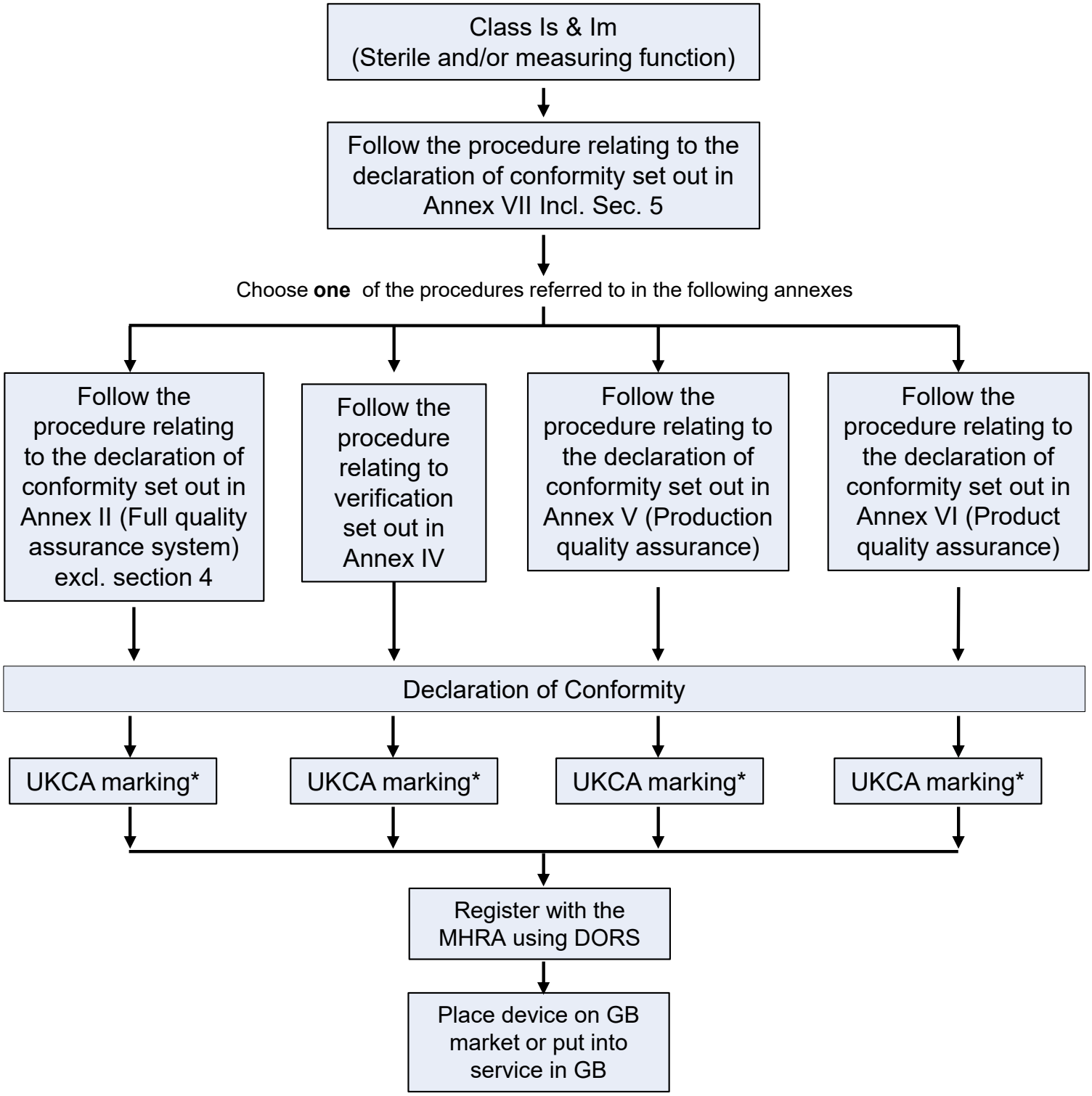
Approved body involvement limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

* Accompanied by the relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

UK MDR 2002 (SI 618, as amended) Class I Conformity Assessment Routes (sterile and/or measuring function)



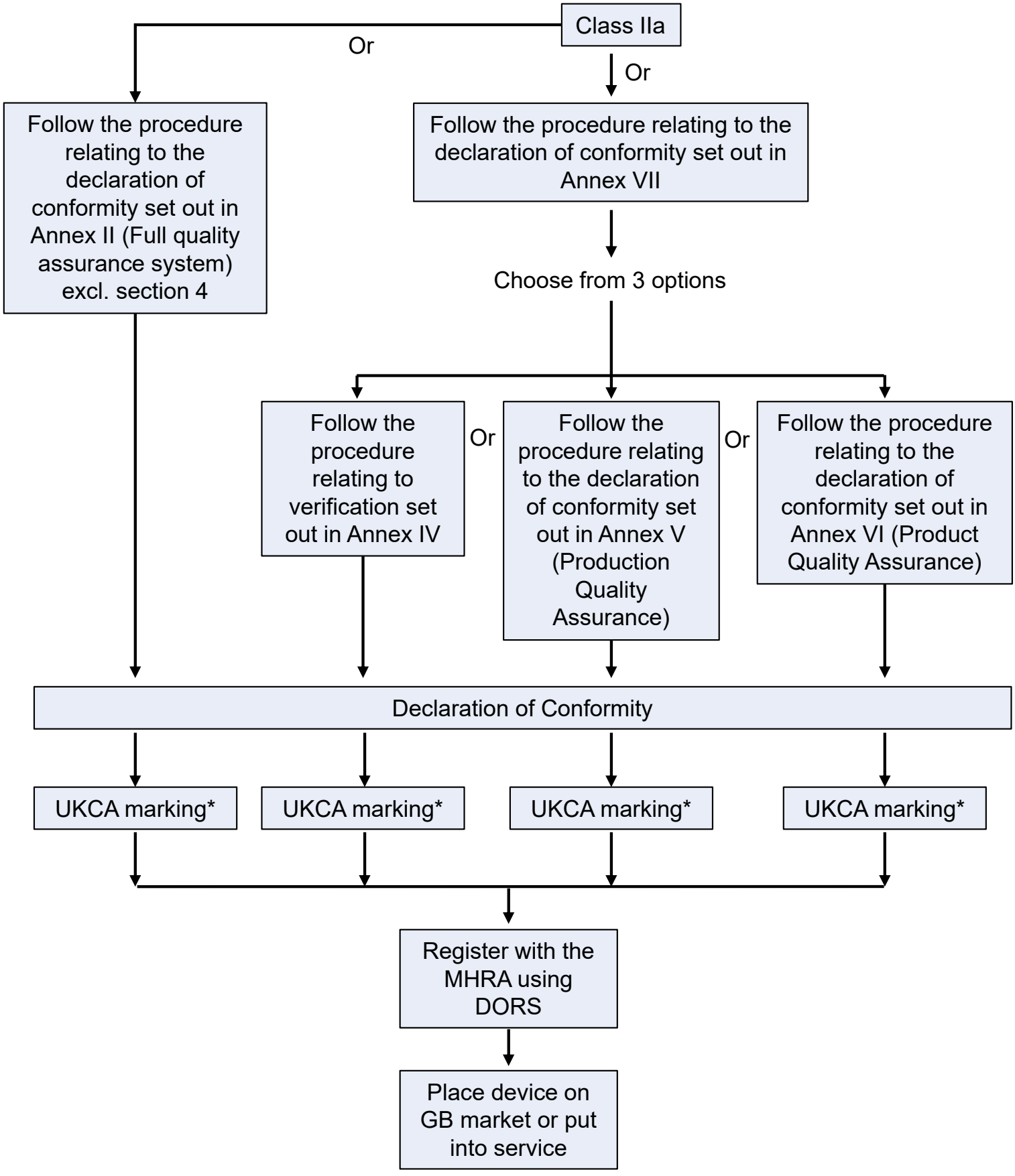
Approved body involvement limited to:

- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

* Accompanied by the relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

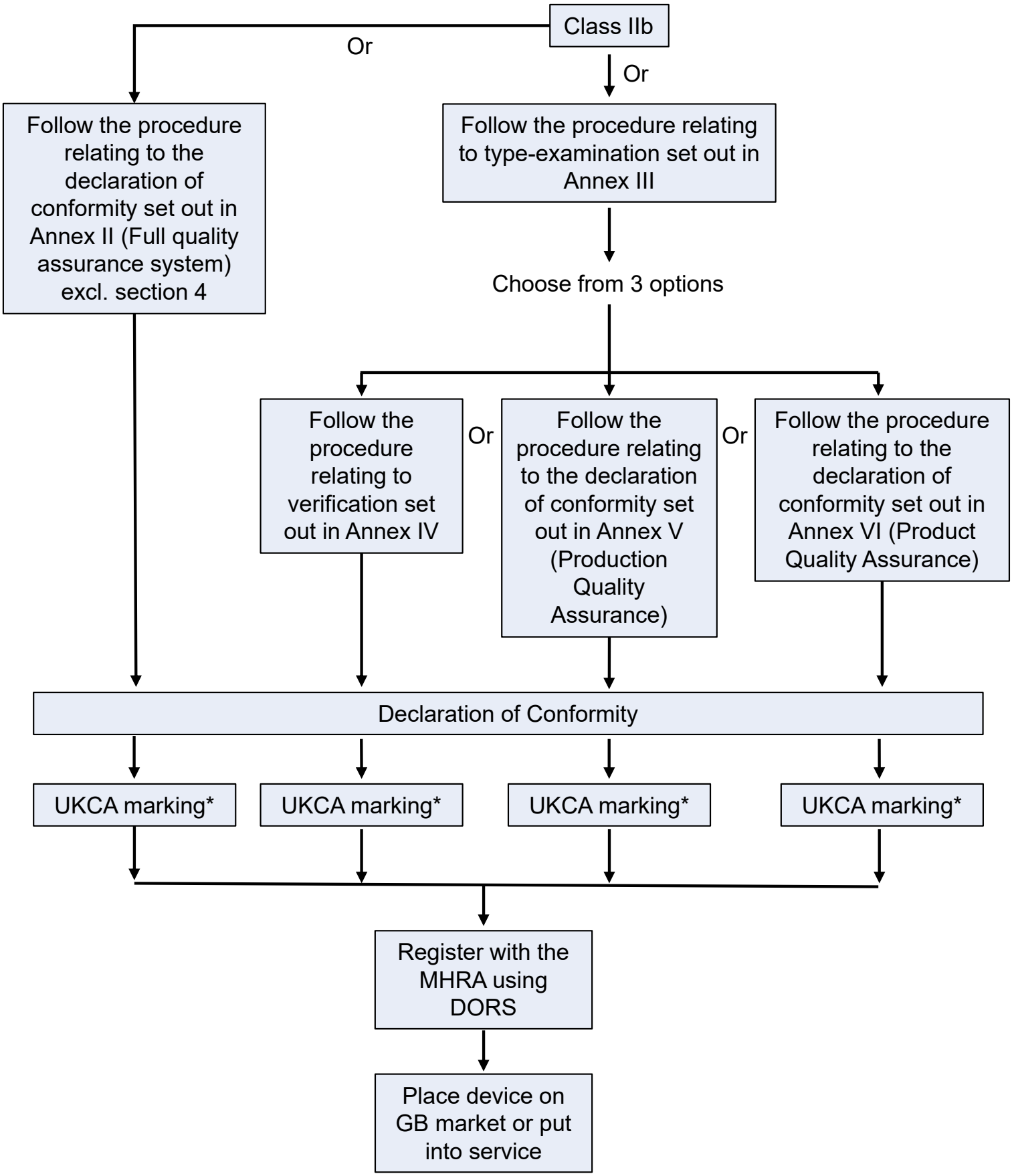
UK MDR 2002 (SI 618, as amended) Class IIa Conformity Assessment Routes



* Accompanied by the relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

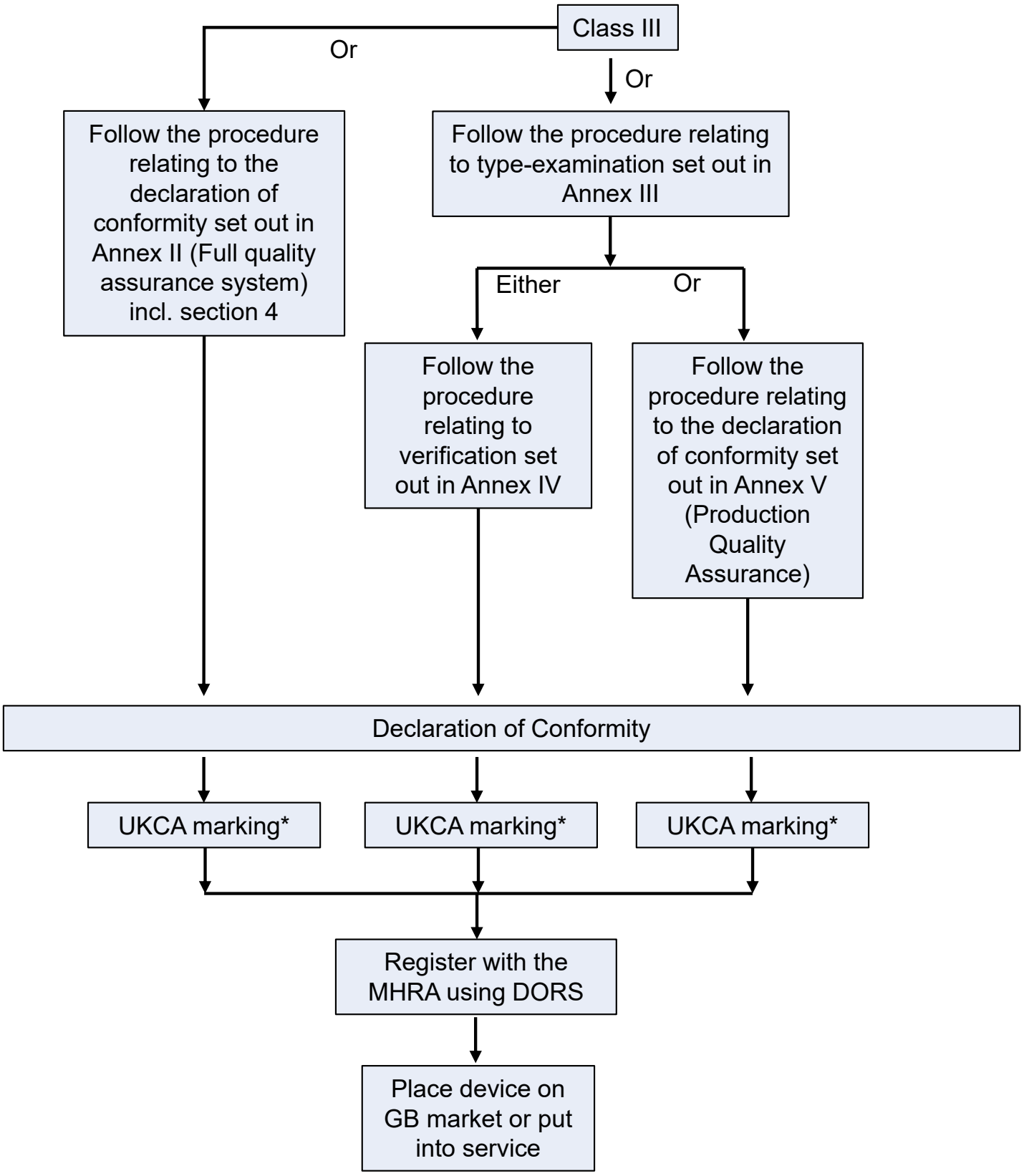
UK MDR 2002 (SI 618, as amended) Class IIb Conformity Assessment Routes



* Accompanied by any relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

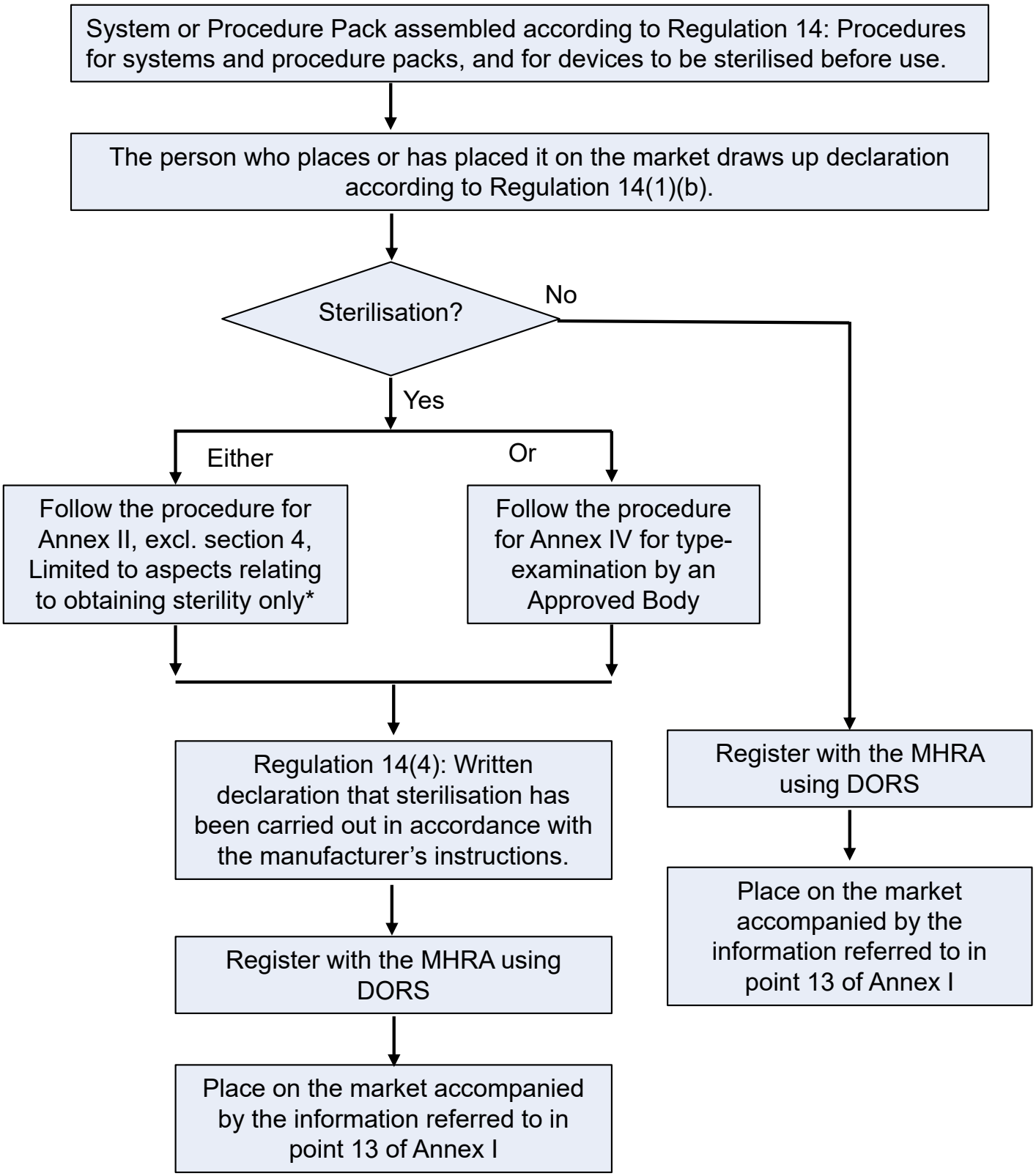
UK MDR 2002 (SI 618, as amended) Class III Conformity Assessment Routes



* Accompanied by any relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

UK MDR 2002 (SI 618, as amended) Systems and Procedure Packs Conformity Assessment Routes

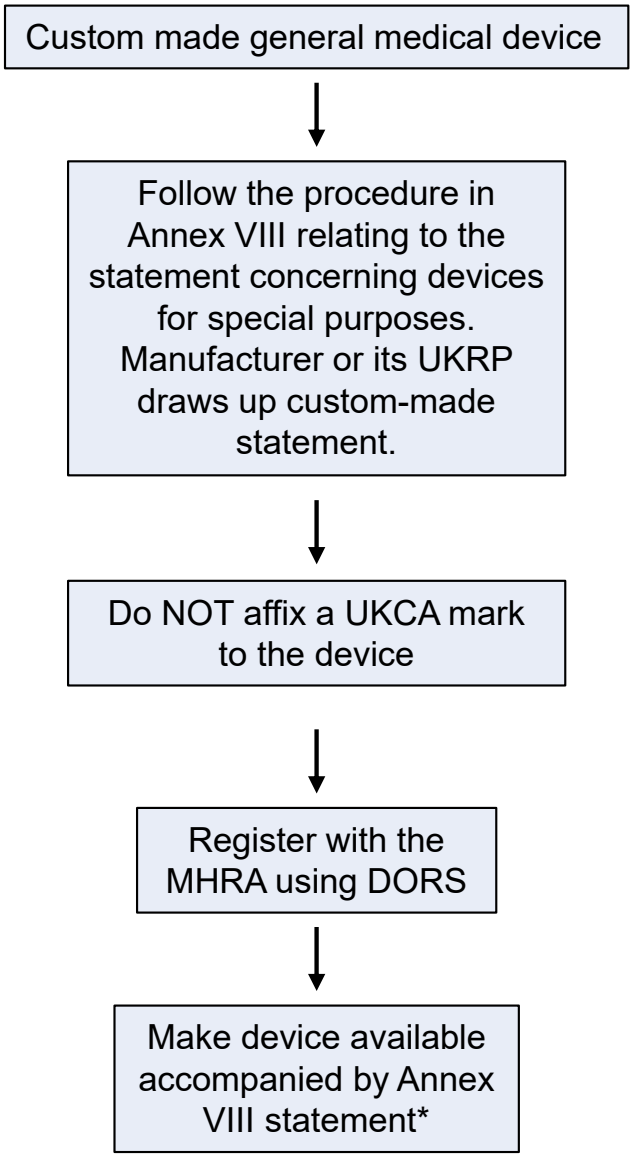


*Approved Body involvement limited to the aspects of the procedure relating to the obtaining of sterility certification.

Devices within the system or procedure pack must already have a declaration of conformity drawn up by their relevant manufacturer(s).

Medicines & Healthcare products Regulatory Agency

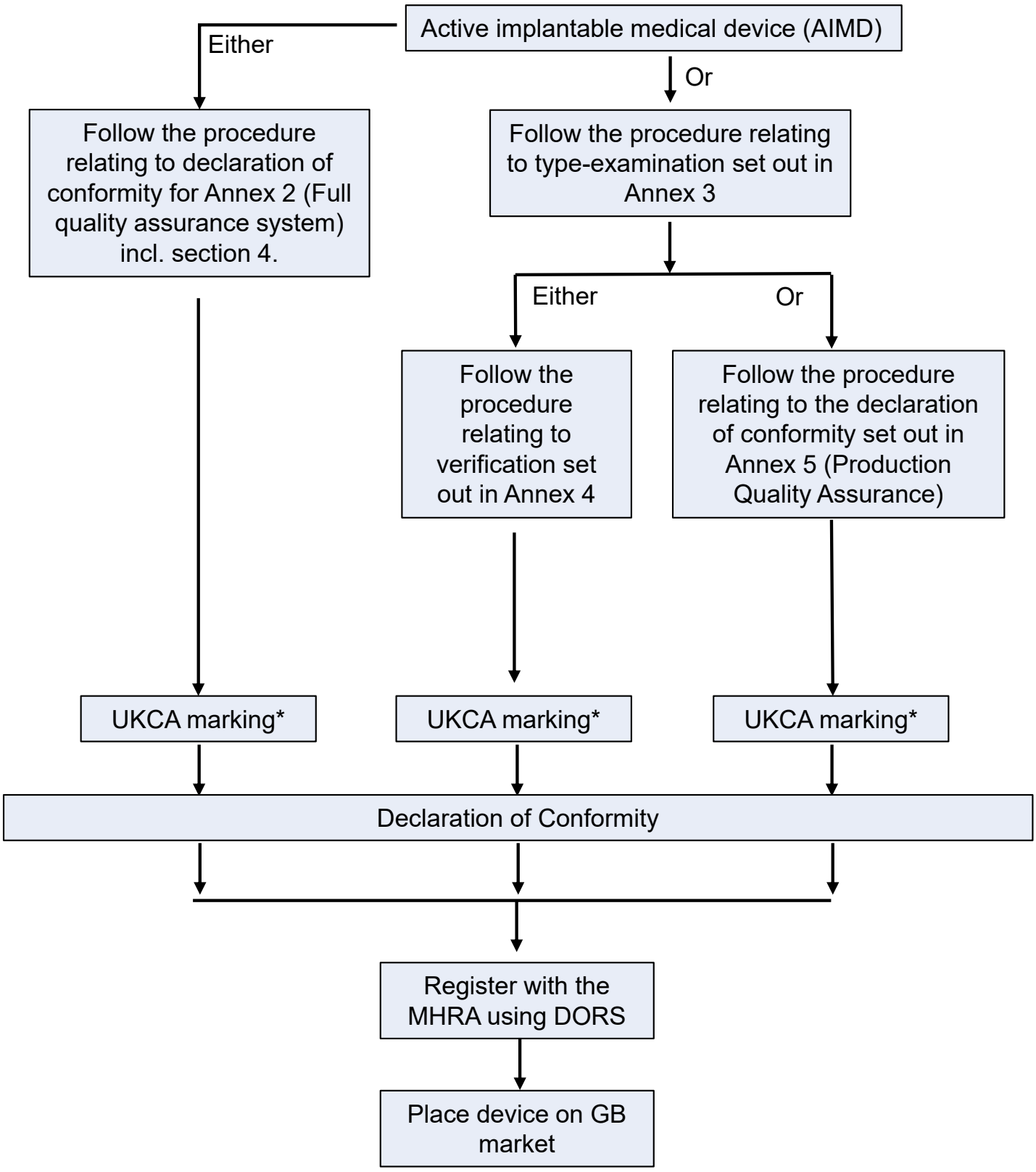
UK MDR 2002 (SI 618, as amended) Custom-made general medical devices Conformity Assessment Routes



* Annex VIII statement must accompany the custom-made device so that it may be made available to the patient on request.

Medicines & Healthcare products Regulatory Agency

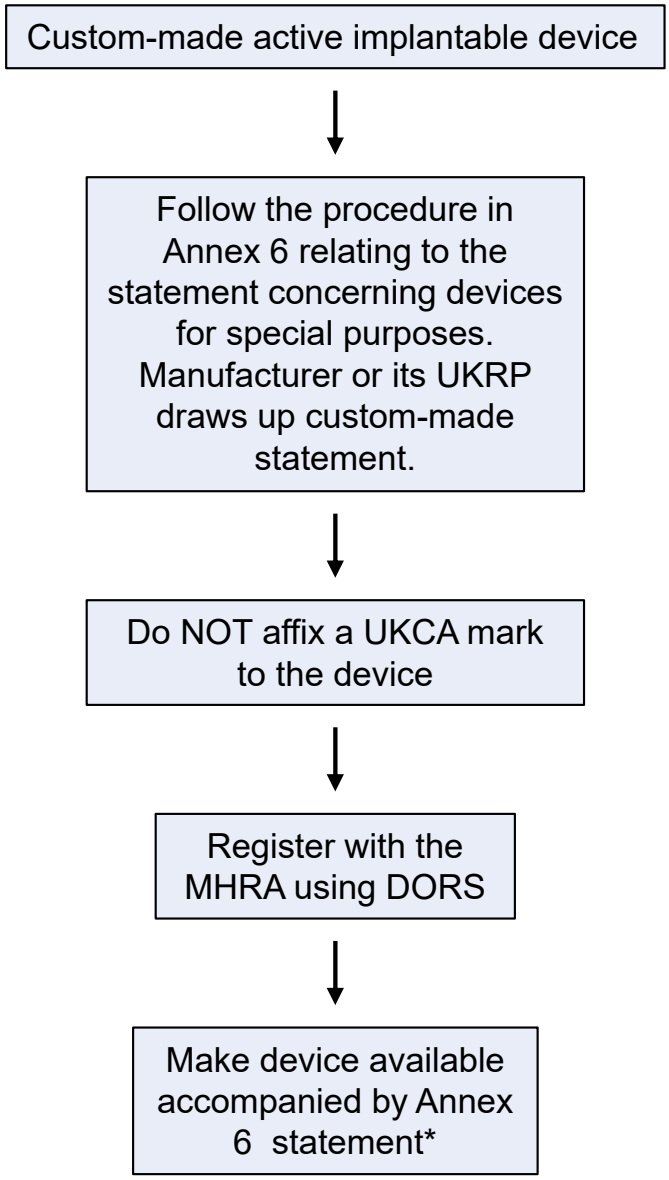
UK MDR 2002 (SI 618, as amended) active implantable medical device Conformity Assessment Routes



* Accompanied by any relevant approved body or conformity assessment body identification number

Medicines & Healthcare products Regulatory Agency

UK MDR 2002 (SI 618, as amended) Custom-made active implantable devices Conformity Assessment Routes



* Annex 6 statement must accompany the custom-made device so that it may be made available to the patient on request.

© Crown copyright 2026

Open Government Licence

Produced by the Medicines and Healthcare products Regulatory Agency.
www.gov.uk/mhra

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit http://www.nationalarchives.gov.uk/doc/open-government-licence or email: psi@nationalarchives.gsi.gov.uk.

Where we have identified any third-party copyright material you will need to obtain permission from the copyright holders concerned.

The names, images and logos identifying the Medicines and Healthcare products Regulatory Agency are proprietary marks. All the Agency's logos are registered trademarks and cannot be used without the Agency's explicit permission.