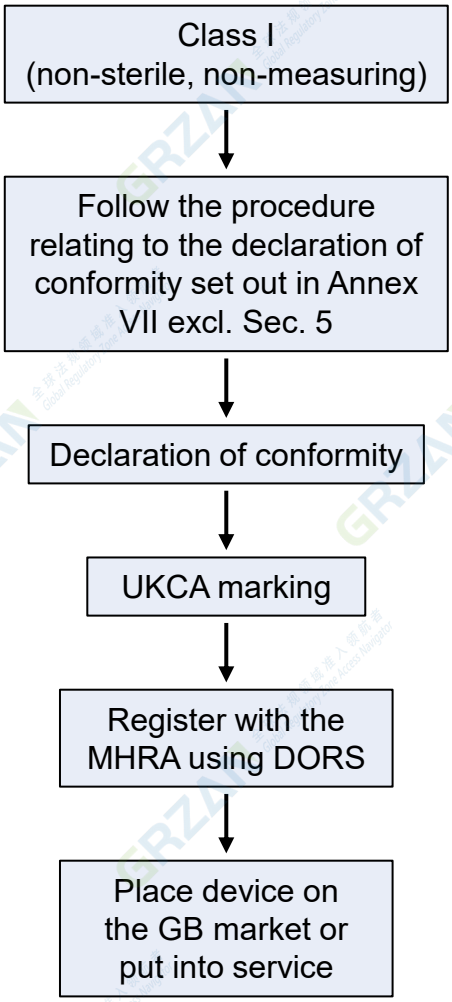
Medicines & Healthcare products Regulatory Agency

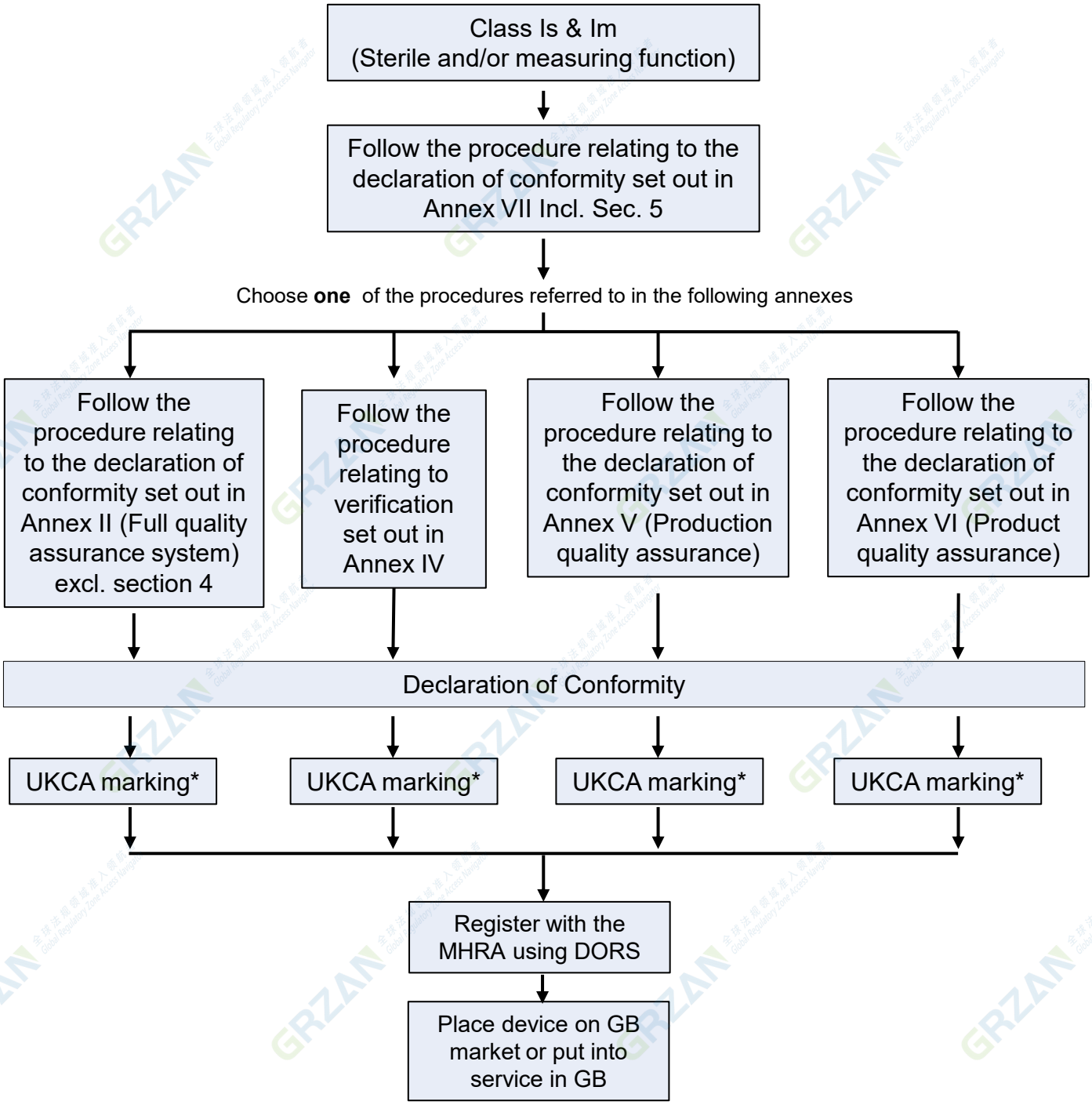
UK MDR 2002 (SI 618, as amended) Class I Conformity Assessment Routes (non-sterile, non-measuring)



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)



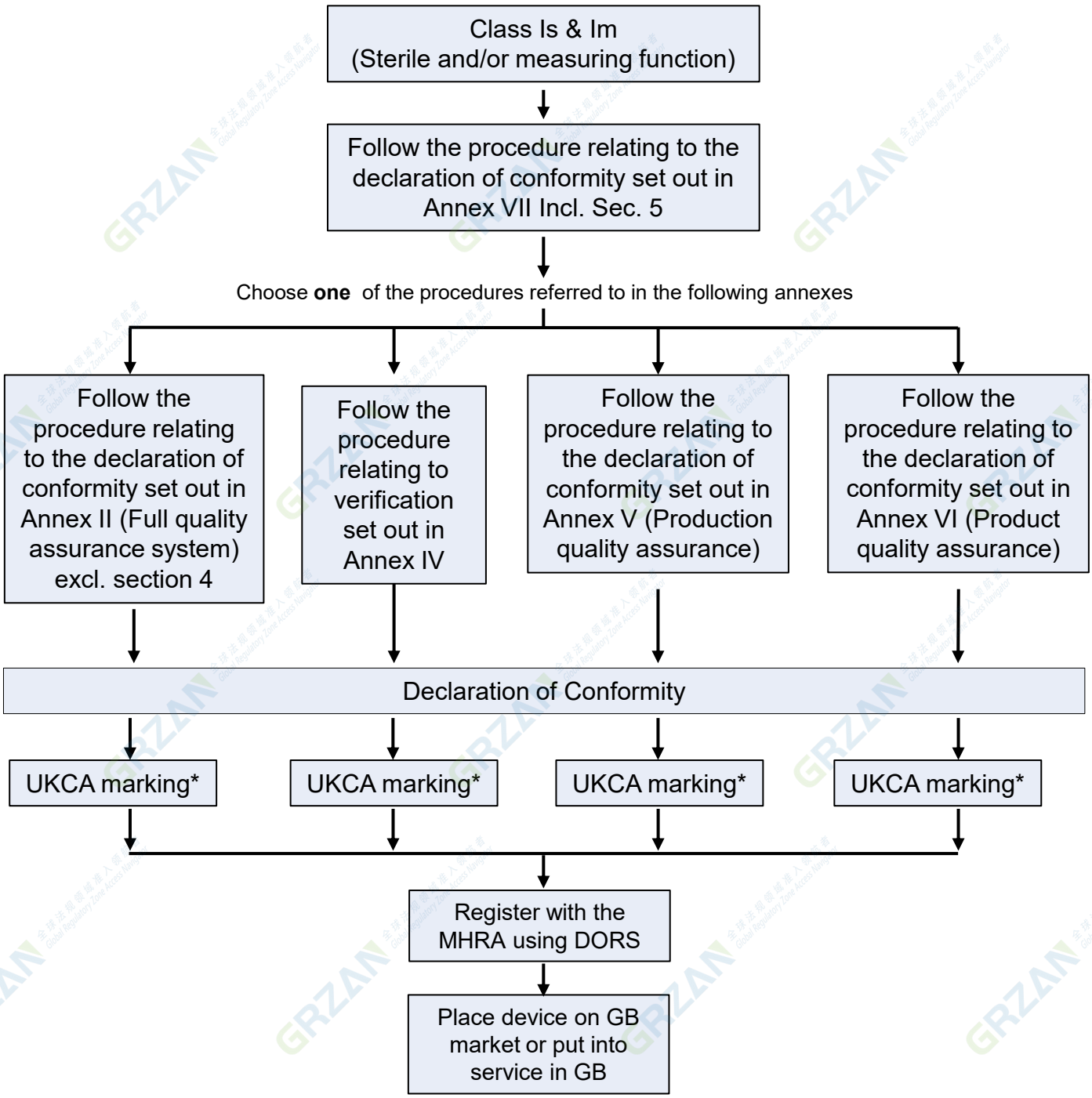
Approved body involvement limited to:

- 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)



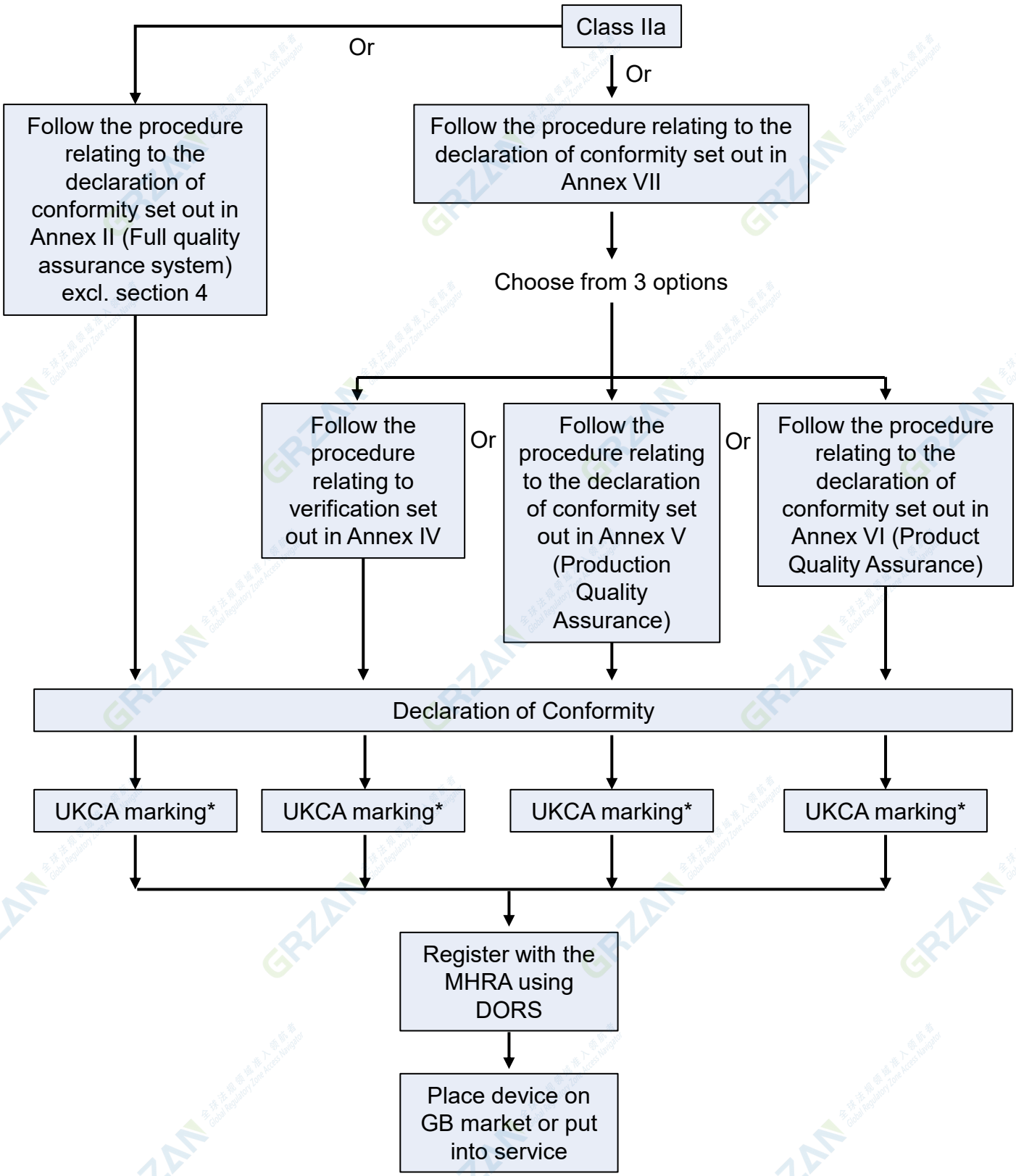
Approved body involvement limited to:

- 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

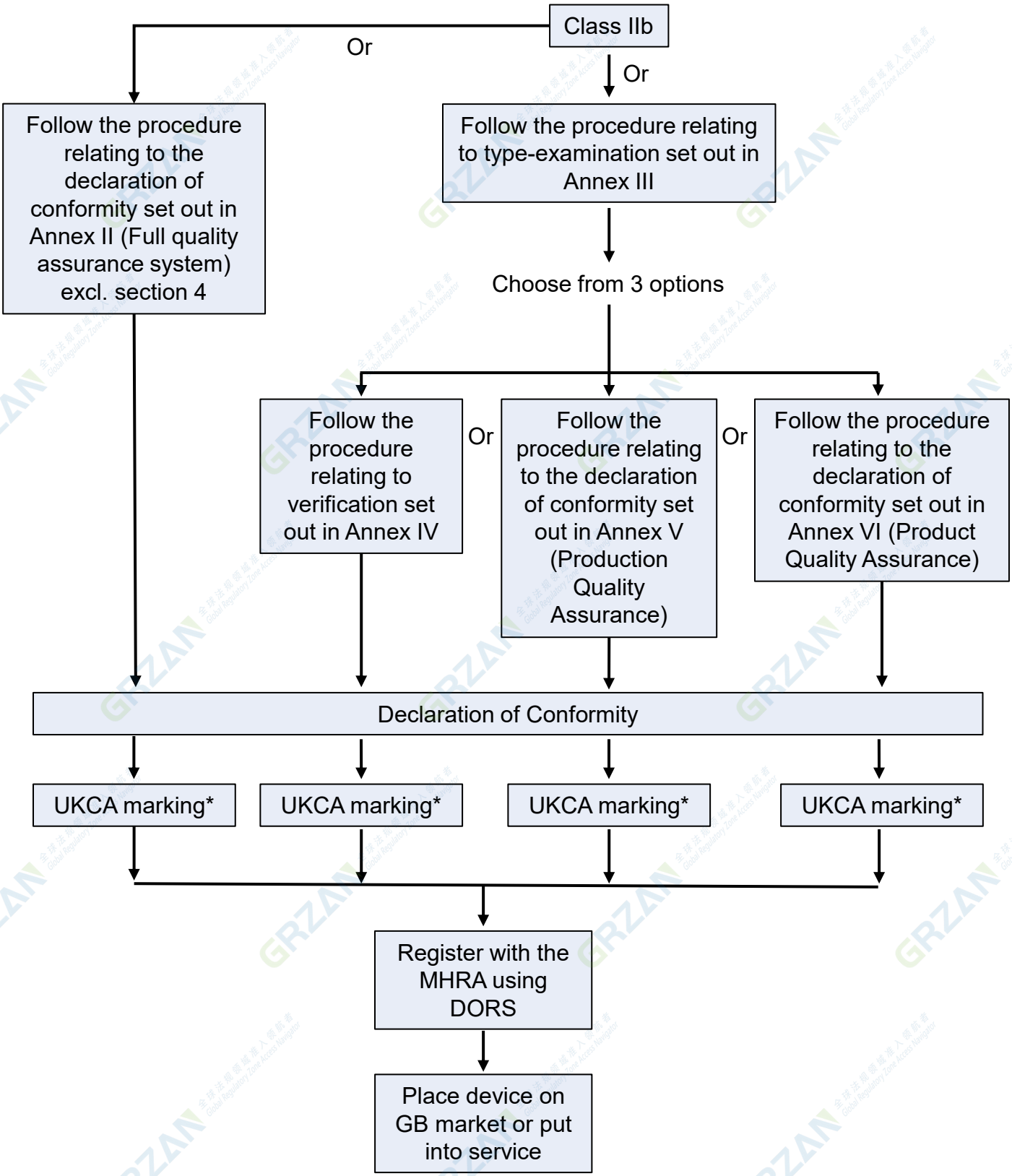
UK MDR 2002 (SI 618, as amended) Class IIa Conformity Assessment Routes



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

Medicines & Healthcare products Regulatory Agency

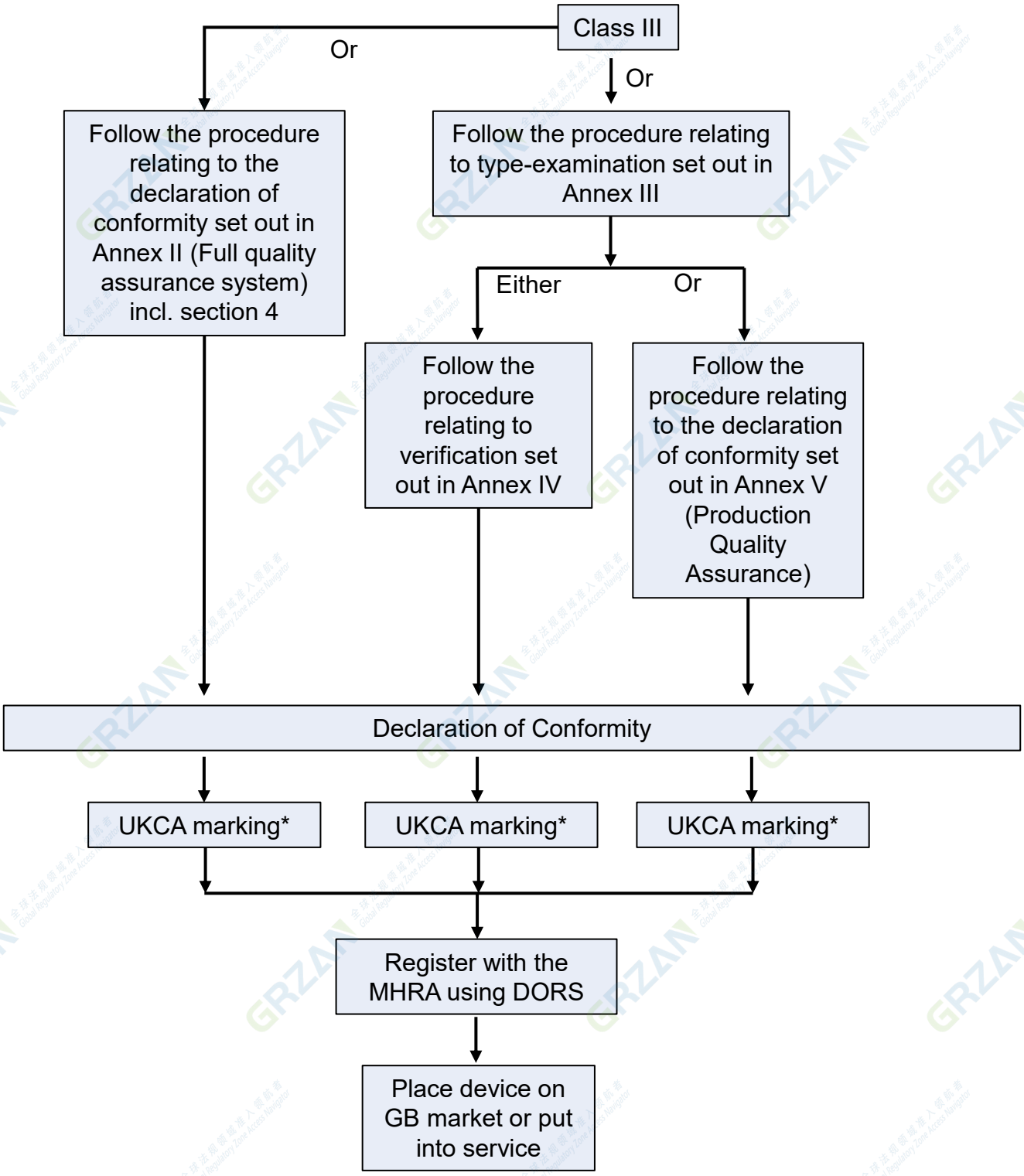
UK MDR 2002 (SI 618, as amended) Class IIb Conformity Assessment Routes



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

Medicines & Healthcare products Regulatory Agency

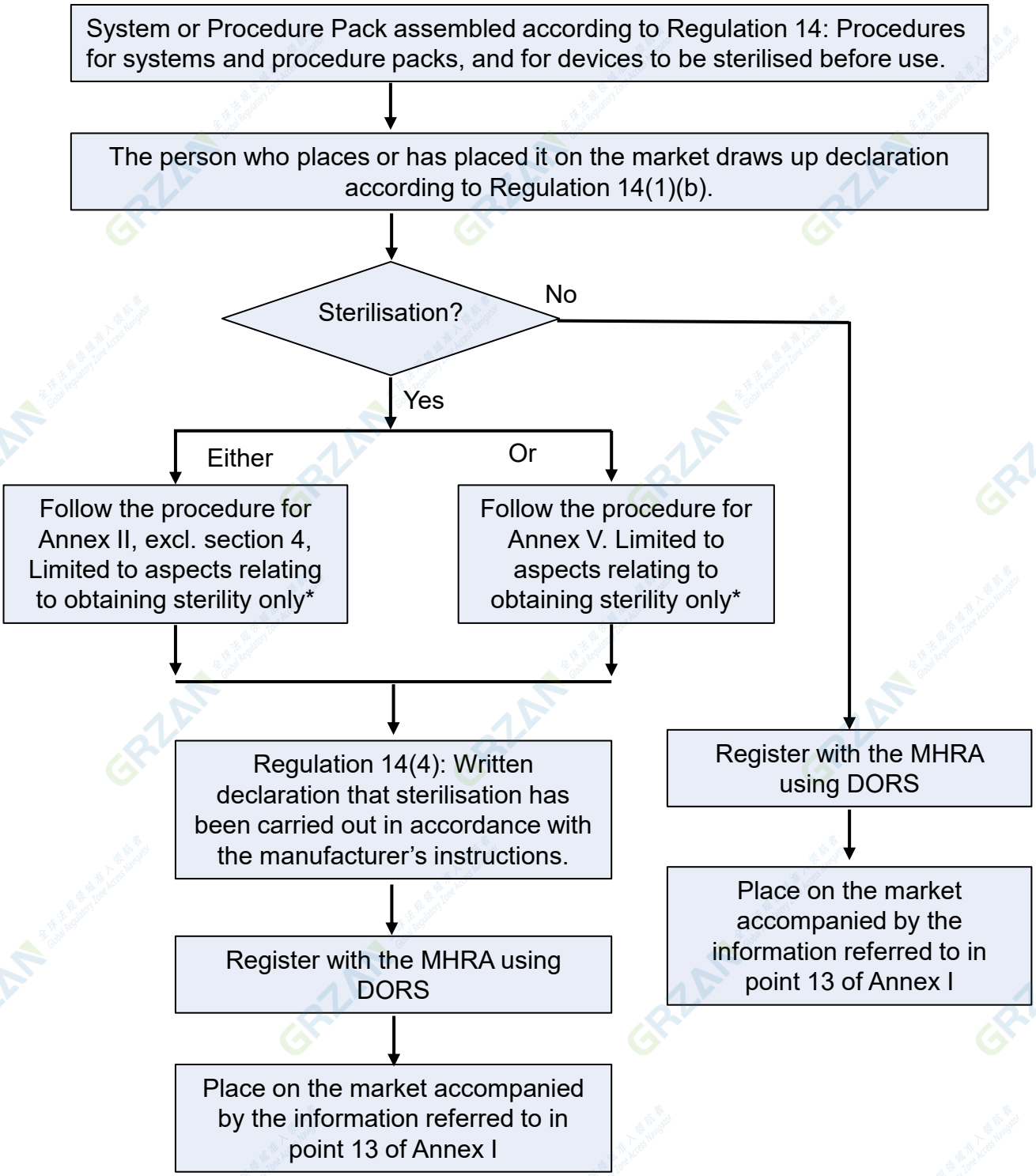
UK MDR 2002 (SI 618, as amended) Class III Conformity Assessment Routes



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

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

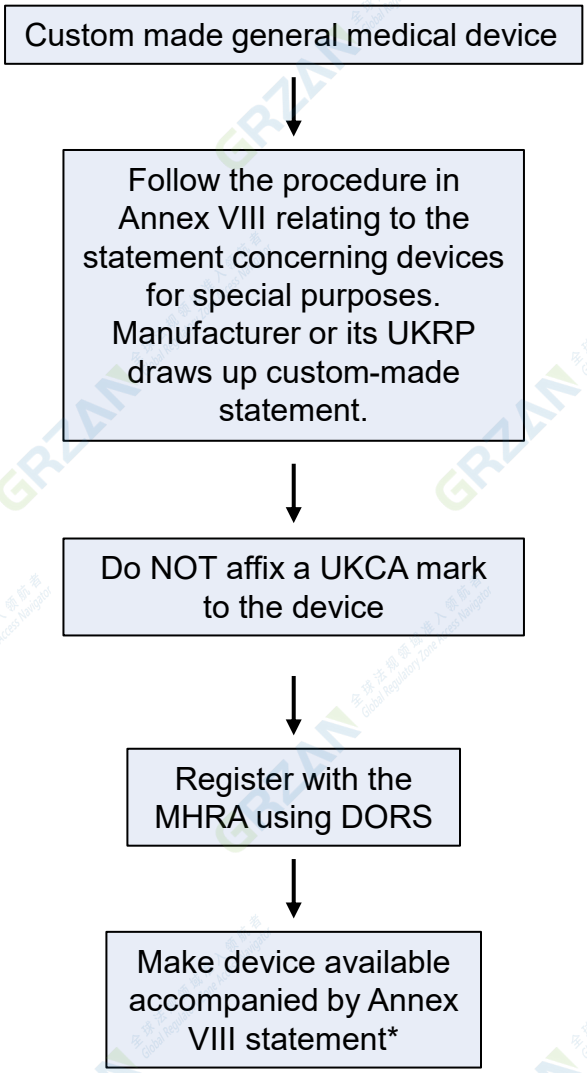


*Approved Body involvement limited to the aspects of the procedure relating to the obtaining of sterility certification.

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

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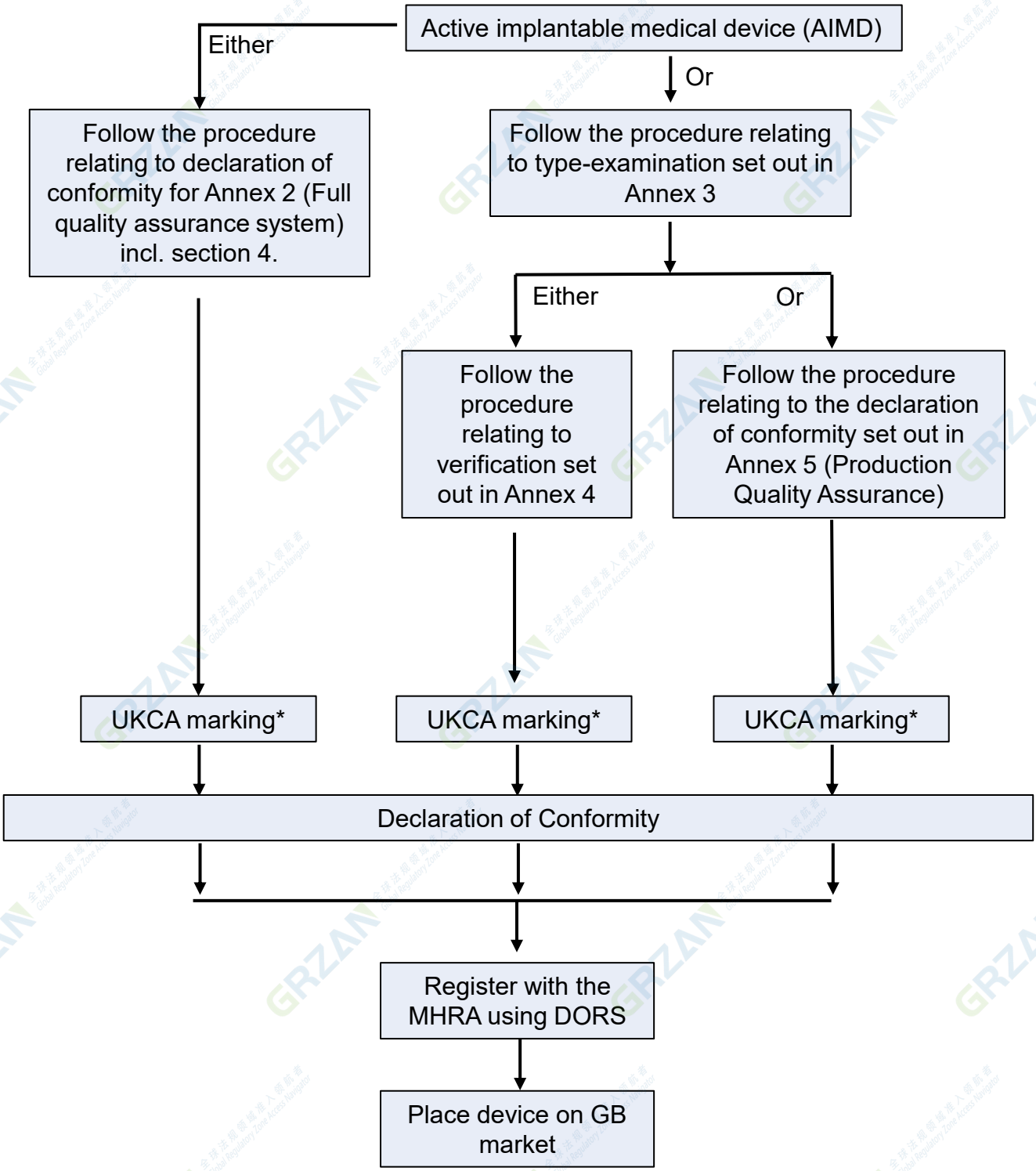
UK MDR 2002 (SI 618, as amended) Custom-made general medical devices Conformity Assessment Routes



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

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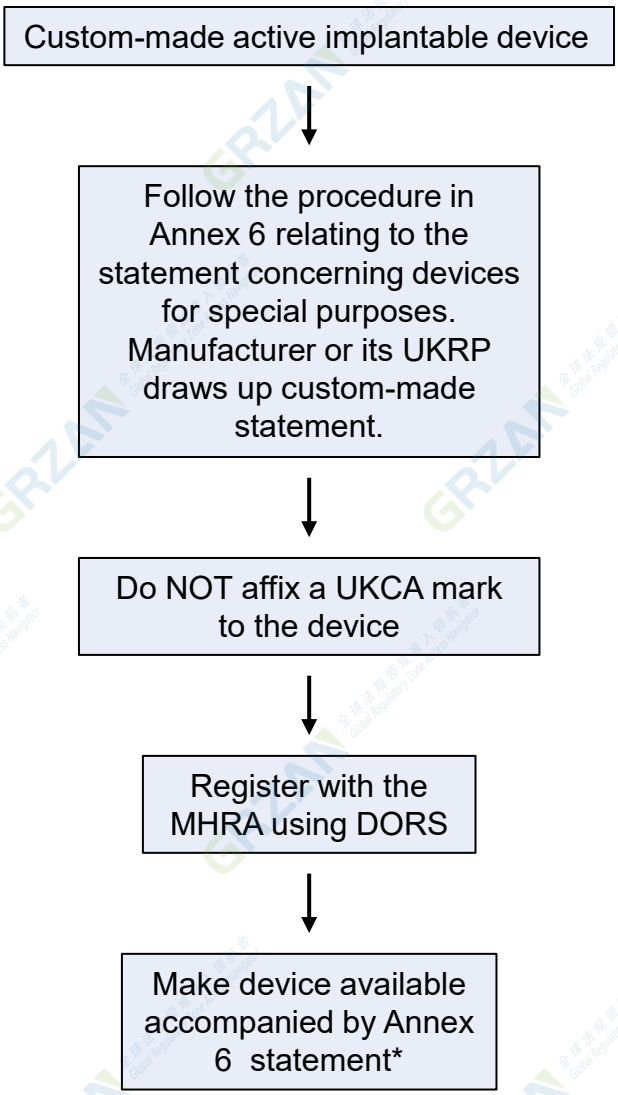
UK MDR 2002 (SI 618, as amended) active implantable medical device Conformity Assessment Routes



* 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.

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