Class I medical devices – routes to CE marking

Device

Annex VII: Prepare technical documentation to support declaration of conformity

Is the device sterile?

Follow Annex IV, V or VI

Does the device have a measuring function?

Notified body involvement required to assess conformity with the metrological requirements *

Compile declaration of conformity

Register with the Competent Authority (CA) (Form RG2)

Affix CE mark

Retain declaration of conformity & supporting evidence for CA Inspection

Market device

* Notified body registration number must appear alongside the CE mark
Class IIa medical devices – routes to CE marking

Device

Either

Or

Annex VII: Prepare technical documentation to support declaration of conformity

Choose from 3 options

Annex II: Full quality assurance audit by a notified body including QMS

Annex IV: Every device/batch verified by a notified body (non-sterile products only)

Annex V: Production quality assurance audit by notified body including QMS (excluding design)

Annex VI: Inspection quality assurance (non-sterile products only) Audit by notified body including QMS (excluding design and manufacture)

Declaration of conformity

Apply CE mark and notified body number

Market device
Class IIb medical devices – routes to CE marking

Device

Either

Annex III: Type examination by a notified body

Or

Annex IV: Every device/batch verified by a notified body (non-sterile products only)

Annex V: Production quality assurance. Audit by a notified body including QMS (excluding design only)

Annex V1: Inspection quality assurance (non-sterile products only). Audit by a notified body including QMS (excluding design & manufacture)

Choose from 3 options

Declaration of conformity

Apply CE mark and notified body number

Market device

MHRA Nov 2015
Class III medical devices – routes to CE marking

Device

Annex II: Full quality assurance. Audit by a notified body including QMS

Either

Annex III: Type examination by a notified body

Or

Annex IV: Every device/batch verified by a notified body (non-sterile products only)

Either

Annex V: Production quality assurance audit by a notified body including QMS (excluding design)

Or

Design dossier examination by a notified body

And

Declaration of conformity

Apply CE mark and notified body number

Market device