Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Common Registration Errors

Letters of designations

a) inconsistent addresses i.e. on what is indicated on the Appian database as well as Companies House
b) no signatures,
c) nothing to indicate an agreement has been made,
d) no letter of designation submitted.
e) UKRPs not established in the UK.
f) mandatory tasks not included

Declaration of Conformities

a) Declaration of Conformity missing key aspects such as product description
b) wrong directives indicated
c) Declaration of Conformity signed and authorised by the UKRP with no manufacturer i.e. no clear evidence that the manufacturer has agreed.

Validation of correct UK approved/Notified body certificate conformity assessment

a) Status of Notified Body inconsistent with Europa Nando website
b) Attaching Declaration of Conformity instead of Notified body certificate
c) Using ISO certificates
d) Missing one or more required EC certificates as indicated in the Appian database

In addition, we have seen a number of falsified EC Certificates of Conformity being submitted, and we encourage those submitting these documents on behalf of the manufacturer to check their veracity before submitting them to the MHRA.

GMDN clarification (e.g. validity of code as medical device)

a) Non-medical devices indicated e.g. PPE, medicines
b) Review of sub-category products – not listed individually, products listed when should be separate GMDN/device
c) Bulk upload data – uploaded wrong (causes technical problems), as above
d) Wrong GMDN chosen- products do not match GMDN description
e) Applicants selecting Custom Made i.e. used to register components rather than adhering to the regulatory definition of a custom made device.