ADELPHI
HEALTHCARE PACKAGING

Supplier Evaluation Checklist:

Purchasing sterile vials for radiopharmaceuticals

This simple checklist helps you check that the sterile, nitrogen-filled vials used for your patient doses meet MHRA requirements.

The vial and manufacturer must meet all requirements in each relevant section to comply with MHRA criteria.

Section A

	YES	NO
1. Does the vial have a **UKCA mark** (if yes, jump to section B)?	☐	☐
2. or a **CE mark** (if yes, jump to section C)?	☐	☐

If you answered 'no' to both, this vial does not meet the required standards.

Section B – the vial has a UKCA mark

1. Can your supplier provide evidence that the manufacturer is registered with the MHRA? ☐
2. Can your supplier provide evidence of MHRA registration for the vial? ☐
3. Does the manufacturer have a notified body? ☐
4. Does the UKCA certification include a scope which covers your intended use of the vial? ☐

   For example, the scope for the Adelphi Anoxos® vial is 'The device is a sterile sealed container filled with sterile nitrogen (an inert gas) intended for the temporary storage of customer produced materials for parenteral administration'.

5. Does the vial supplier have a UK Declaration of conformity detailing the part number of the product? ☐

	YES	NO
6. Is the legal manufacturer based in the UK?	☐	☐

If yes, you have completed all the necessary checks.
If no, please complete section D.

Section C – the vial has a CE mark

If the CE mark is in accordance with Medical Device Regulation 2017/745 (EU MDR), please complete section C.i

If the CE mark is in accordance with Medical Device Directive 93/42/EEC (EU MDD), please complete section C.ii

---

Section C.i – The vial has a CE mark in accordance with the EU MDR

1. Can your supplier provide evidence that the manufacturer is registered with the MHRA? ☐
2. Can your supplier provide evidence of MHRA registration for the vial? ☐
3. Does the CE certification have a scope which matches your intended use of the vial? ☐
4. Is there an EU Declaration of conformity detailing the part number of the product? ☐
5. Can they provide confirmation of EUDAMED registration showing the appointed EU Authorised Representative and valid Mandate? ☐

Complete section C.iii

Section C.ii – The vial has a CE mark in accordance with the EU MDD

1. Can your supplier provide evidence that the manufacturer is registered with the MHRA? ☐
2. Can your supplier provide evidence of MHRA registration for the vial? ☐
3. Does the CE certification have a scope which matches your intended use of the vial? ☐
4. Does the certification include a notified body letter declaring they have an extension to the certificate in line with Article 120 of the MDR? ☐
5. Is there an EU Declaration of conformity detailing the part number of the product? ☐
6. Can they provide confirmation of EUDAMED registration showing the appointed EU Authorised Representative and valid Mandate? ☐

Complete section C.iii

Section C.iii

	YES	NO
1. Is the legal manufacturer based in the UK?	☐	☐

If yes, you have completed all the necessary checks.
If no, please complete section D.

Section D – The legal manufacturer is based outside of the UK

1. Does the manufacturer have an appointed UK Responsible Person? ☐
2. Do they have written evidence from the UK responsible person that they have the authority to act as such? ☐
3. Is the name and address of the UK responsible person included on **one** of the following: ☐
    1. On the product labelling or outer packaging
    2. On the 'Instructions For Use' (applicable to UKCA marking only)
4. Does the manufacturer have a UK-based importer? ☐

You have now completed all the necessary checks.

If your supplier can demonstrate the above points, you can be confident that your vial is in compliance with MHRA requirements.

ADELPHI
HEALTHCARE PACKAGING

The Medical Device Regulations and Directives detailed in this checklist are:
Regulation EU 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices (MDR)
Medical Device Directive 93/42/EEC as amended by 2007/47/EC (MDD)
Medical Devices Regulation 2002 (S18) as subsequently amended by the EU Exit Regulation of 2019 (S1 791) and 2020 (S1 1478) (UK MDR)

All information provided in this checklist is correct at the time of publishing. Please contact our regulatory team if you require further guidance: info@adelphi-hp.com