**Notification of parallel import of self-test IVDs**

**Importer details**

Company name

Company address

What will the medical device be called when it is sold/supplied in the UK

**Named contact**

Name

Company name (if different from above)

Company address (if different from above)

**Details of device being imported**

**Give a full description of the device to be imported from the EEA country**

(eg type of device, appearance, no.)

EEA country from which it is to be imported:

Name of the device in the EEA country from which it is to be imported

Name of manufacturer

(as defined in Article 1.2 of the IVD Directive, whose name and address is on the product label.)

**Has the relevant trade mark owner been notified of the intention to import the device into the UK?**

Yes [ ]  specify the person and company name and address:

No [ ]

This is not an obligation under the IVD legislation but required under trade mark legislation/case law.

**Supplier(s) in the EEA from whom the device will be obtained**

List the name and address of each of the suppliers

**Is the device intended by the manufacturer to be a self-test in vitro diagnostic device?**

Yes [ ]  No [ ]  if No, please specify

**Does the device differ in any way from the manufacturer’s device?**

Yes [ ]  specify how:

No [ ]

Any change which affects the safety or intended purpose of the self-test in vitro diagnostic device would result in the parallel importer taking on full responsibility for its compliance with the IVD Directive.

**Outline repackaging, transport and storage details:**

Note: Attach copies of the English language labelling and leaflets to be used with the re-packaged device and specify the source of English language text (e.g. manufacturer’s translation, importer’s translation).

**Declaration**

We declare that the repackaging (including translation of the labelling and leaflets) transport and storage does not affect the safety or intended use of the device covered by the manufacturer’s CE marking.

**Electronic Signature**

Name

Company name

Person’s function

Date of signature

**Email the form to:** IVDPI@mhra.gsi.gov.uk