**DT 1B form: IN VITRO DIAGNOSTIC MEDICAL DEVICES**

The information on this form MUST be completed IN FULL or it will be returned.

If you are applying for the listing of a blood glucose reagent strip you will need to complete the CRSDF01 form if you are intending to provide accompanying services.

Please check the boxes to confirm that you are attaching the relevant certificates.

Please circle the Regulations that apply to this device(s):

**EU IVDD (98/79/EC) UK MDR 2002 EU IVDR 2017/746**

If registered under the EU MDR 2002 or the UK MDR 2002, please state the category of the of the IVD:

**General IVD Self-testing IVD**

**Annex II List A IVD Annex II List B IVD**

If registered under the EU IVDR 2017/746, please state the classification status of the device and the Rule which applies under Article 47 and Annex VIII of the Regulations:

**Class A Class B Class C Class D**

For both registrations, please supply:

**Confirmation of Registration with a Competent Authority**

**Enclose a copy of the Declaration of Conformity.**

Name of person who has signed the declaration (in block capitals):

Their position in the company:

*This is a declaration made by the manufacturer of a medical device to confirm that the product meets the requirement of the relevant directive). The declaration is usually made on company headed paper and signed by a senior person within the company. It should make reference to the product name or group of products to which it belongs and also make reference to which directive the product complies to. The Declaration of Conformity must cover all products being applied for on the DT1 Form. Where product codes have been used on the DT1A Form and on the Declaration of Conformity, applicants should make sure that the codes match each other. A document not bearing a signature will be invalid*

**Certificate issued by the Notified Body or UK Approved Body confirming the conformity route followed**

I confirm that the information provided in this DT1B Form is correct at the time of completion and that I will inform NHS Prescription Services of any changes that occur during the application process and subsequent to a successful listing. I am also aware that this application will not be processed if any of the above is not provided.

Signed: Print Name:

A scanned handwritten signature should be applied

Date:

*For more information on the application procedure, please see Drug Tariff Part IX Guidance to Manufacturers and Suppliers of Medical Devices available at:*

*http://www.nhsbsa.nhs.uk/PrescriptionServices/3399.aspx*

*or e-mail us on* [*pixie@nhsbsa.nhs.uk*](mailto:pixie@nhsbsa.nhs.uk)

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| --- | --- | --- | --- | --- | --- | --- |
| **Ref: CRSDF01 Declaration Form: Service Provision in relation to Chemical Reagents** | | | | | | |
| To: | Drug Tariff Team  NHSBSA  NHS Prescription Services  Email to: pixie@nhsbsa.nhs.uk | | | Company Stamp  (or if a head office, attach a signed letterhead as authorisation) | | |
| **Manufacturer Details** | | | | | | |
| Manufacturer Name | | |  | | | |
| Address | | |  | | | |
| Postcode | | |  | | | |
| **Manufacturer Declaration** | | | | | | |
| I declare that the services listed below which are provided by      in relation to the chemical reagents we manufacture and which are listed under Part IX of the Drug Tariff will continue to be provided for the period to 31 March 20xx  **Services Provided:** | | | | | | |
| **Completed by:**  *(authorised signature)* | |  | | | **Telephone number:**  *(in case of queries)* |  |
| **Name:**  *(please print name)* | |  | | | **Position:** |  |
| **Date:** | |  | | |