**DT1 1B form for: CLASS I (measuring function or sterile), CLASS IIA, Class IIB, Class III MEDICAL DEVICES**

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

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

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

EU MDD 93/42/EEC UK MDR 2002 EU MDR 2017/745

**Declaration of Conformity** **[ ]**

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

Their position in 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 DT1A Form. Where product codes have been used on the DT1 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.*

**Please state the Annexes which apply to the conformity assessment(s). Details are given on the certificate issued by the Notified/Approved Body:**

Name of Notified/Approved Body:

Notified/Approved Body number on certificate: Expiry date:

**If the device is Class III, include an EC type examination /design certificate [ ]**

*Notified Bodies are agencies that assess whether a manufacturer’s processes meet the requirements of the relevant directives. They provide the manufacturers with certification to the relevant annex of the directive. The number under the registration mark displayed on the product packaging should match the notified body number on the certificate. The certificate should be within the expiry date at the time of application.*

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*