**DT1 Form Part A**

**ONLY send a sample IF requested to do so**

**APPLICATION FOR APPROVAL OF PRODUCTS UNDER PART IX OF THE DRUG TARIFF FOR GP AND NON-MEDICAL PRESCRIBING**

**3. Proposed Drug Tariff Category. Please state a relevant category along with a subcategory in the Drug Tariff OR propose a New Drug Tariff category if a corresponding section for your product does not exist yet.**

**2. Names and Address of Applicant:**

**Name and Address of Manufacturer: (if different)**

**Telephone Number:**

**Email Address:**

**1. Product Name:**

Please state the trade name under which the product is to be launched or is already known in the UK. The name proposed should match the name which is presented on the product sample.

**7. Price and Order Codes:**

This should be the trade price excluding VAT

**6. Pack Size(s) (i.e. the number of devices in a pack to be ordered by a prescriber):**

**5. Main indication/use:**

**4. If comparable products including those from other manufacturers/suppliers are already listed in the Drug Tariff, please list their names, prices and product codes (if available) here, where possible these should all be from the same category/sub-category:**

**10. Please indicate which Medical Device Directive(s) and conformity mark(s) apply to your device(s):**

1. CE/UKCA marked under EU MDD (Directive 93/42/EEC) or EU IVDD (98/79/EC)
2. CE/UKCA marked under EU MDR (2017/745) or EU IVDR (2017/746)
3. UKCA marked under UK MDR 2002

Class of device:

**9. Please confirm how the product will be made available.**

Please indicate which is applicable:

1. ‘Readily available through the normal wholesale network’ is regarded as a product that is stocked by the wholesaler as a standard line.
2. You may choose to supply the product ‘on equivalent terms’ which is regarded as the supply of the product without extra charges for example delivery, postage & packing etc. (applicable to devices listed in Part IXA and R)

**8. Estimated Patient Population:**

This is the approximate number of people in the UK population affected by the condition for which your product is designed.

Anticipated Volume of Sales:

This is the approximate number of units you are aiming to sell per year.

**11. Date medical device was registered with the MHRA**

**MHRA registration number:**

**13. Supply to Northern Ireland**

Please indicate Yes or No

Do you intend to supply this device on the Northern Ireland Tariff? Yes/No

If Yes

Is the product CE marked? Yes/No

If No

*\*The device cannot be supplied to Northern Ireland\**

If Yes

Is the manufacturer a GB based company or from outside the EU? Yes/No

If Yes

Please state the EU-based or Northern Ireland-based Authorised Representative.

\*To be completed for GB manufacturers or non-EU manufacturers only\*

**12. Name and address of the UK Responsible Person**

**14.**

I confirm that the information provided in this DT1A 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 confirm that the device(s) are ready to supply on FP10.

Signed: Print Name:

Please apply a handwritten scanned digital signature

Date:

Please now complete the appropriate DT1B Form applicable to the class of device and the regulatory route used - EU MDD or EU MDR and email both forms to:

pixie@nhsbsa.nhs.uk