**Blood products – Checklist of required documentation**

*Please note: The Blood product checklist should be completed in cases where a medical device (Blood Bags) is in combination with a biological agent (anticoagulant). In addition to this checklist, a supplier is expected to submit complete UNFPA Questionnaire for Medical Devices.*

**Submitter:**

Name of submitter: Click here to enter text.  
Address: Click here to enter text.  
Contact person’s name: Click here to enter text.  
Email: Click here to enter text.  
Phone: Click here to enter text.

**Product identification:**

1.1 Active biological/ pharmaceutical ingredient(s) (use INN if any): Click here to enter text.

1.2 Generic name of the product: Click here to enter text.

1.3 Trade (proprietary) name (if any): Click here to enter text.

1.4 Dosage form: Click here to enter text.

Tablets  Capsule  Injectable  Syrups/oral liquids

Other (Please specify): Click here to enter text.

1.5 Strength per dosage unit (if applicable): Click here to enter text.

1.6 Route of administration: Click here to enter text.

Oral  I.M. I.V. S.C. Other (Please specify)

1.7 Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients). Please also indicate the standard for each ingredient (e.g. PhEur, USP). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged:

Click here to enter text.

1.8 Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. contains alcohol 10%, paraben…….):

Click here to enter text.

**Biological Agent – Checklist for required documentation**

Documents to be submitted (**where applicable**) must be true and valid copies.

Complete pharmaceutical dossier for the biological component in combination with the medical device

Certificate of analysis of the three latest batches of blood product confirming that the blood product complies with the current revision PhEur or USP monograph.

When CPP is not available attach official statement of licensing status.

Attach release specifications and shelf-life (regulatory) specifications.

List of countries where product is registered, including the specific product name, license number in each country and copies of registration certificate.

Copy of GMP certificate by SRA OR the most recent WHO Inspection report.

Filled out declaration from applicant.