SOP:
Document-Code (e.g. EU-SOP)
Document-Version (e.g. Version 1.0)

Title:	**EUBIS SOP Master Document**
Valid from:	Effective date. Expiry date. A document control procedure must be established to guarantee a regular review of documents and to keep the history of documents (previous versions).
Replaces Version:	Document-Code and Document-Version
Changes:	- Please describe/list the relevant changes that have been made in comparison to the previous version of the document - Reasons for changes
Distributor:	Original: Quality management office Copy-Identification Number (Example): 1, 2, 3 etc. the use of electronic copies is optional

Written by:	**Reviewed and authorised by:**		
Date:	Date:		
Name of person(s)	Name of person(s)		

1. Objective

2. Area of application

3. Roles covered by the SOP (job description, personnel responsibilities)

Name of the key personnel involved in the process covered by the SOP including the responsible/qualified persons (as defined by the Directive's).
This information can be alternatively given in the site-master file and/or handbook according to the organisational chart and/or job description.

4. Description Operating Procedure

4.1 Process Flow-Chart

4.2 Define Critical Points (Risk analysis)

4.3 Description of the work activities

5. Procedure for Non Conformance (Commission Directive 2005/62/EC – Art. 9)

Define measures or regulation to be taken if there are deviations from the defined working description or in case of unexpected errors.

The corrective and preventative action system should ensure that existing product nonconformity or quality problems are corrected and that recurrence of the problem is prevented. The blood establishment should have methods and procedures in place to input product or quality problems into corrective and preventative action system.

Requirements for these quality elements are not subject to this document level (SOP). In general these regulations are included on a higher ranked document level (e.g Quality management handbook/Site-Master File/General Procedure).

6. Documentation

The documentation of procedures and records is essential to a quality assurance system. It ensures that work performed is standardised, and that there is a traceability of all steps in the collection, manufacturing, testing, release/issuing, storage and distribution of blood components.

All records shall be kept for a minimum of 15 years (Directive 2002/83/EC).

7. Annex

- **Literature** (e.g MedLine-publications of methods)
- **References** (e.g. Manufacturer manuals, test procedure descriptions)
- **Terminology**
- **related SOP-Documents** (e.g Equipment log-books)
- **Records and/or protocols used for documentation**
  (e.g. Form sheets used in this SOP, Cleaning and desinfection plan, donor recall record)

Important requirements to be referred to in the SOP:

- **Directive 2002/98/EC**
- **Quality manual / Site Master File** (according to Annex I Part B, Art 11(1), Directive 2002/98/EC)
- **Commission Directive 2004/33/EC**
- **Commission Directive 2005/61/EC**
- **Commission Directive 2005/62/EC**
- **National legislation**
- **National guidelines**

Important notice :
The aim of this project is not to provide a operating procedure to be used in an institution, but rather to provide the tools by which one can build up an standard operating procedure (SOP). The idea is to provide a logical framework which can be used by all institutions in a variety of different logistical and functional situations.

The EUBIS SOP-Master is thought to give an example on how to set-up a SOP following best practice for blood establishments based on the EU blood legislation (Directive 2002/98/EC and 2005/62/EC).