Guidelines for the Blood Transfusion Services

27.1: Introduction

http://aws-lon-jpac.targetservers.uk/red-book/chapter-27-specification-for-labelling-consumables-used-in-therapeutic-product-production/27-1-introduction

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This chapter defines the requirements of the UK Blood Transfusion Services for the labelling by the manufacturer of ‘stand-alone’ consumable medical devices (critical consumables) used in the production of therapeutic blood components and tissues.

These devices are distinct from blood bags (either individual bags or within a blood pack or apheresis set assembly, including those pre-filled with anticoagulant or preservatives) that are described in Chapter 26 and tissue containers which are described in Chapter 24.

This specification applies to:

- stand-alone intravenous (IV) and other solutions including:
  - preservatives and additives (e.g. platelet additive solution)
  - saline
  - dextrose and dextran
  - anticoagulants
  - pathogen inactivators
- filters (e.g. leucodepletion, prion filtration)
- fluid transfer sets
- injection sites, clamps, one-way valves.