



Part 2

Product Certification

1. Product Information REF Number:ASN00P4117 Lot Number: 4117210822 List Number: P-4117

Product description: Bowl//Tubing/Bag assembled

Sterile Load Number	Date of Sterilization	Quantity	Expiration Date	Component
4117210822	2021/08/23	20000	2025/08/21	N/A

2. Testing

2.1 Nigale sterile disposables are manufactured from materials tested and certified to be sale for use in short duration (less than 24 hours) circulating blood contract applications. Fluid path materials to our knowledge meet European Pharmacopoeia standards and meet the requirements for biocompatibility and biological safety.

2.2 Physical Testing

The standards of the SFDA Good Manufacturing Practices (GMP) are met. PVC tubings and bags correspond to EP/DAB VI 1.2.1.1 and VI 2.2.2.2.

2.3 Sterility and Pyrogenicity

The product is sterile and pyrogenfree. It meets requirements of EP. The sterilization process has been validated following ISO 11737.2-1998 Guidelines.

Nigale, hereby, certifies that the listed batch meets all above mentioned requirements and all Nigale defined requirements for performance, safety, sterility and pyrogenicity.

I certify that appropriate controls are in place to assure records are reviewed prior to release of product for distribution and that the authorization to release products for distribution is limited and controlled. The above products are according to 93/42/EEC.

Quality Manager

Name Title Date: 2021-09-01