

The management system of

Neomedic Limited
Unit 2, Leavesden Lodge, 1A Leavesden Road,
Watford, WD24 5FR, UK



has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 November 2019 until 26 November 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 November 2022
Issue 20. Certified since 12 March 2001

Authorised by



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Neomedic Limited

ISO 13485:2016

EN ISO 13485:2016

Issue 20

Detailed scope

Design and manufacture of:

Single-use sterile blood bags

Manufacture of single-use sterile medical devices:

Surgical gloves

Hypodermic needles

Auto-disable syringes

Syringes with and without needle

Gauze swabs non-X-ray detectable

Gauze swabs X-ray detectable

Laparotomy sponges pre-washed X-ray detectable

Blood lancets disposable

Endotracheal tubes

Feeding tubes

Guedel airways

Infusion sets with needle

IV cannulae with wings and injection port

Laryngeal masks

Foley latex catheters

Nasal oxygen cannulae

Nelaton catheters

Oxygen masks

Scalp vein sets

Foley all-silicone catheters

Stomach tubes

Suction catheters with thumb control

Tracheostomy tubes

Transfusion sets with needle

Urine bags

Yankauer suction sets

Laparotomy sponges pre-washed non-X-ray detectable

Manufacture of non-sterile medical devices:

Examination gloves nitrile

Examination gloves vinyl

Examination gloves latex

Adhesive plasters

Wound dressings

Crepe bandages

Support bandages

Undercast padding

Umbilical cord clamp

Alcohol swabs

Manufacture of in-vitro diagnostic test kits:

Blood collection tubes

Urine pregnancy test kits

Urine chemistry test kits for professional use (not for home use)



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