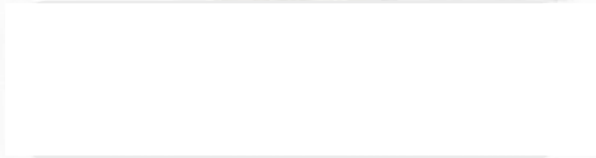


Certificate

The management system of



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 04 September 2019 until 28 January 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 28 January 2021
Issue 2. Certified since 28 January 2000

Expiry date of last certificate: 31 March 2019
End date of last surveillance audit: 07 December 2018

Authorised by

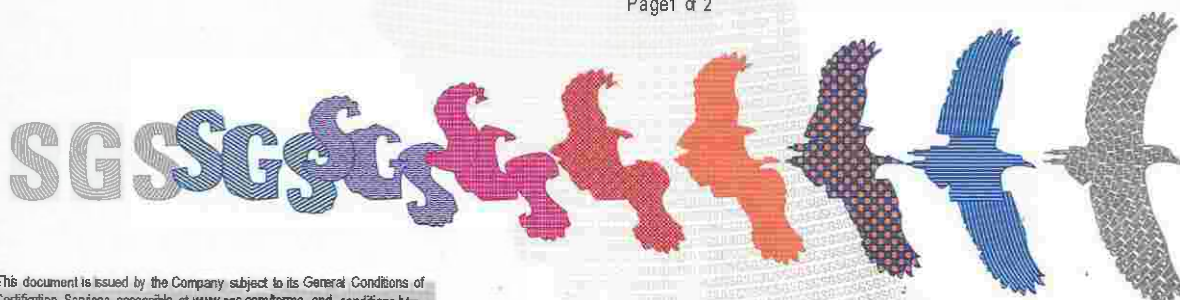


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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

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ISO 13485:2016 EN ISO 13485:2016

Issue 2

Detailed scope

Design and manufacture of single-use medical devices including:

- Syringes and needles
- Sterile syringes (including insulin, BCG & Mantoux syringes) with needles;
- Sterile Hypodermic needles,
- Tubes and catheters
- Sterile Nelaton catheters,
- Sterile rectal catheters, Sterile Tracheal tubes,
- Sterile duodenal tubes acc. to Levin,
- Sterile Ryle's tubes with x-ray contrasting line,
- Sterile Naso-duodenal tubes,
- Sterile Endobronchial suction tubes,
- Sterile feeding tubes, Sterile Suction connecting tubes,
- Sterile Surgical drainage tubes with or without x-ray contrasting line,
- Sterile Drainage vacuum sets,
- Sterile Catheter redon drains (with or without x-ray contrasting line)
- Sterile Catheters for pleurocentesis
- Sterile Abdominal catheters
- Sterile Thorax catheters,
- Infusion transfusion and perfusion sets

Sterile infusion sets including:

- Sterile infusion set with metal needle
- Sterile infusion set with plastic needle
- Sterile Scalp vein sets "Buterfly" for infant infusion
- Sterile Nasal oxygen catheter,
- Sterile Oxygen masks type Eschmann
- Sterile surgical gowns for use in operation room
- Sterile urine bags,
- Sterile surgical drapes and covers,
- Sterile PE examination gloves,
- Sterile plastic throat spatula, Sterile gynecological spatula,
- Sterile Umbilical cord clamps,
- Sterile syringes (including insulin, BCG & Mantoux syringes) without needles;
- Sterile Stomach tubes, Sterile infusion set without needle
- Non sterile Plastic cup

Provision of Ethylene Oxide Sterilization in accordance with ISO11135-1:2014



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