

EC Certificate Production Quality Assurance System: Certificate

The management system of

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

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

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 16 December 2019 until 27 January 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 28 January 2000 and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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