EC Certificate Full 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 II (excluding Section 4)

For the following products

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

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

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 1

Detailed scope

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 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

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.