EC Certificate Full Quality Assurance System: Certificate JP19/030582

The management system of

UNISIS CORP.

Saitama Plant

2675-1 Nishikata, Koshigaya-shi,
Saitama, 343-0822 Japan

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 12 March 2021 until 24 October 2022
and remains valid subject to satisfactory surveillance audits.
Issue 4. Certified since 24 October 2011

Certification is based on reports numbered JP/YOK 8093

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Head of Notified Body

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UNISIS CORP.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

- **Sterile and non-sterile single use epidural anaesthesia kit**
- **Sterile single use combined spinal epidural anaesthesia kit**
- **Sterile single use spinal anaesthesia needle**
- **Sterile and non-sterile single use epidural anaesthesia needle and Sterile and non-sterile single use nerve blockade needle**
- **Sterile and non sterile single use introducer**
- **Sterile and non-sterile single use biopsy needle**
- **Sterile single use epidural anaesthesia catheter**
- **Sterile single use injection needle**
- **Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintain sterile conditions"**
- **Sterile single use loss of resistance syringe**

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.

Additional facilities

Head Office	4-11-4 Taito, Taito-ku, Tokyo, 110-0016 Japan
Logistic/Sterilization Center	2623-1 Nishikata, Koshigaya-shi, Saitama, 343-0822 Japan
Hokkaido Plant	1-2-8 Wattsu Industrial Complex, Kita-Hiroshima-shi, Hokkaido, 061-1281 Japan

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