EC Design Examination Certificate: Certificate JP19/040523

# UNISIS CORP.

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

Device Identification:

**Sterile UNIEVER Combined Spinal Epidural Anaesthesia Minitrays**

Intended Purpose of Device:

**Injection of analgesic or anaesthetic medication into the subarachnoid cavity and epidural space in order to reversibly block spinal nerve conduction and to provide analgesia and muscle relaxation**

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on Medical Devices, Annex II, Section 4**

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 16 December 2019 until 16 December 2021
Issue 1. Certified since 16 December 2011
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered JP/YOK 8094 dated 07 June 2017

Addenda to that report have been issued on the following dates:

| Addendum Date | Reason for Addendum |
|---|---|
| N/A | N/A |

Authorised by

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