Certificate JP11/040295

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

# 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 07 December 2021 until 24 October 2023
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 11. Certified since 24 October 2011

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

Authorised by

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

21HC 13485 2016 0421 M2



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# UNISIS CORP.

## ISO 13485:2016
## EN ISO 13485:2016

Issue 11

Detailed scope

**Design, development and manufacture of sterile and non-sterile single-use spinal, epidural, nerve blockade, angiographic, introducer, guide, biopsy and injection needles, sterile and non-sterile epidural catheters, sterile and non-sterile loss of resistance syringes, sterile membrane filters, sterile and non-sterile epidural anaesthesia kit, sterile spinal and epidural anaesthesia kit , sterile and non-sterile anaesthesia filters**

Additional facilities

| | |
|---|---|
| **Head Office** | **4-11-4 Taito, Taito-ku, Tokyo 110-0016 Japan** |
| **Logistics/ 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** |

UKAS MANAGEMENT SYSTEMS
0005



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