

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 16 February 2021 until 24 October 2023  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 30 September 2023

Issue 10. Certified since 24 October 2011

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

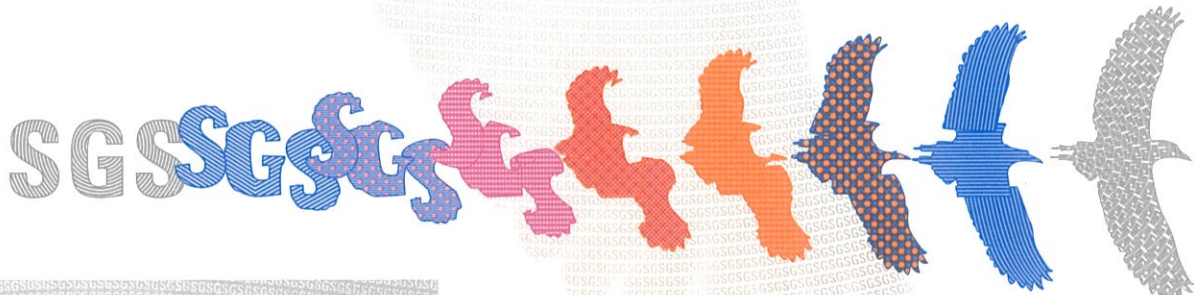


0005

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](http://www.sgs.com)

HC SGS 13485 2016 0118 M2

Page 1 of 2





Certificate JP11/040295, continued

## UNISIS CORP.

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



Issue 10

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 epidural anaesthesia kit, sterile spinal and epidural anaesthesia kit, sterile metal dilator and 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**



0005