

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

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 and sterile and non-sterile single-use heat moisture exchanger

This certificate is valid from 16 November 2023 until 10 July 2026 and remains valid subject to satisfactory surveillance audits.

Issue 15. Certified since 24 October 2011

Certified activities performed by additional sites are listed on subsequent pages.

*Jonathan M. Hall*

Authorised by

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# UNISIS CORP.



ISO 13485:2016

EN ISO 13485:2016

Issue 15
<b>Sites</b>
UNISIS CORP. Saitama Plant 2675-1 Nishikata, Koshigaya-shi, Saitama 343-0822, Japan 1. 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, and sterile and non-sterile anaesthesia filters 2. Design and development of sterile and non-sterile single-use heat moisture exchanger
UNISIS CORP. Head Office 4-11-4 Taito, Taito-ku, Tokyo 110-0016, Japan Sales 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 and sterile and non-sterile single-use heat moisture exchanger
UNISIS CORP. Logistics/Sterilization Center 2623-1 Nishikata, Koshigaya-shi, Saitama 343-0822, Japan 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, and sterile and non-sterile anaesthesia filters
UNISIS CORP. Hokkaido Plant 1-2-8 Wattsu Industrial Complex, Kita-Hiroshima-shi, Hokkaido 061-1281, Japan 1. Manufacture of sterile and non-sterile single-use heat moisture exchanger 2. Manufacture of non-sterile single use spinal, introducer, guide, biopsy and injection needles



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