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
Medical devices - Quality management systems - Requirements for regulatory purposes

For the following activities

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 and non-sterile epidural anaesthesia kit, sterile spinal and epidural anaesthesia kit, sterile and non-sterile anaesthesia filters and sterile and nonsterile single-use heat moisture exchanger
2. Provision of Ethylene Oxide Gas sterilization service for medical devices

This certificate is valid from 10 July 2026 until 10 July 2029 and remains valid subject to satisfactory surveillance audits.
Issue 17. Certified since 24 October 2011

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

L. Moran

Authorised by
Liz Moran
Business Manager

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 - www.sgs.com

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

UNISIS CORP.

ISO 13485:2016/EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Issue 17

Sites

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 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 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.
Packaging/Sterilization Center: 2623-1 Nishikata, Koshigaya-shi, Saitama 343-0822, Japan

1. 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 and non-sterile epidural anaesthesia kit, sterile spinal and epidural anaesthesia kit, and sterile and non-sterile anaesthesia filters
2. Provision of Ethylene Oxide Gas sterilization service for medical devices

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

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on Terms and Conditions | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.