EC Design Examination Certificate: Certificate JP19/040524

UNISIS CORP.

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

Device Identification:

Sterile UNIEVER Spinal Anaesthesia Needles

Intended Purpose of Device:

Injection of local anaesthetic into the subarachnoid space in order to block neurotransmission, reduce pain and relax muscles withdrawal of cerebrospinal fluid for testing and the intrathecal injection of medicinal products

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 06 August 2022
Issue 1. Certified since 22 May 2012
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered JP/YOK 8733 dated 04 December 2017

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

Addendum Date	Reason for Addendum
25 April 2019	Changes to labelling and IFU to add "NRFit" branding

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at https://www.sgs.com/en/certified-clients-and-products/certified-client-directory. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.