

EC Design Examination Certificate: Certificate KR19/81826276

Tae-Chang Industrial Co., Ltd

(Gongju Plant) 8-18 Bojeokdong-gil, Useong-myeon
Gongju-si, Chungcheongnam-do, 314-864, Korea

Device Identification:

Sterile Spinal Needles (Quincke Bevel type and Whitacre Pencil Point type)

Intended Purpose of Device:

**Sterile spinal needles intended for the subarachnoid injection
of anaesthetic agents into the spine for spinal anaesthesia prior
to surgery, for lumbar puncture for pain management
and for the extraction of cerebrospinal fluid for diagnostic purposes**

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 01 February 2021 until 24 May 2024

Issue 4. Certified since 11 August 2010

and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL 600655 dated 30 July 2010

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

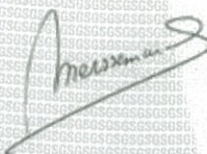
Addendum Date

N/A

Reason for Addendum

N/A

Authorised by



Global Medical Devices Certification Manager

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

LPMD5009 - Certificate CE1639 Annex II section 4 ECDE Rev. 2

Page 1 of 1



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.