EC Certificate Full Quality Assurance System: Certificate KR19/81826310

The management system of

MedicalPark Co., LTD

#601/623/624, Knowledge-Industry Center, Bundang Suji U-Tower,
767, Sinsu-ro, Suji-gu, Yongin-si, Gyeonggi-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Breast biopsy system for making an incision, suction, collection and removal of breast tissue (Model: BXS100);

Sterile single-use breast biopsy probe for making an incision, suction, collection and removal of breast tissue for use in Breast biopsy system (Model: BXC145, BXC140, BXC135, BXCW135, BXCW140 and BXCW145);

Sterile single-use core biopsy instrument kit for biopsy of human tissue (Model: BXFG1410, BXFG1610)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 11 February 2020 until 24 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 25 August 2015
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered KR/SEL Y-PC/15410

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