



MEDICAL PARK Co., Ltd.

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

EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Brand Name: BEXCORE

Product Name: VABB (Vacuum-Assisted Breast Biopsy) Needle

Model Name: BXC135, BXC140, BXC145, BXCW135, BXCW140, BXCW145

Classification: Class IIa (Annex IX Rule 6, Council Directive 93/42/EEC as amended by Directive 2007/47/EC)

Conformity Assessment Route: Annex II, Excluding Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Notified Body: SGS Belgium NV

SGS House Noorderlaan 87 2030 Antwerp Belgium

Applied Standards : EN ISO 13485:2016, EN ISO14971:2012, EN ISO 10079-1:2009, EN ISO10993-1:2009/ AC:2010, EN ISO 10993-5:2009, ISO10993-10:2010, ISO10993-11:2009, EN ISO 10993-6:2006, ISO11135:2014, ISO14644-1 & 2:2015, EN ISO 10993-11:2009, EN ISO 11137-1:2006/ A1:2013, EN ISO 11137-2:2013, ISO14644-1:1999, ISO14644-2:2000, EN1041: 2008, EN980: 2008, MEDDEV 2.7.1/Rev.4, MEDDEV 2.12.1/Rev.8, MEDDEV 2.12.2/Rev.2

Manufacturers Registered Name: MEDICALPARK Co., Ltd.

EC Representative: JaviTech e.K.

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EC Certificate: KR19/81826310

GMDN Code No.: 12734[Needle, biopsy, single-use]



Signature:

Date: 04 Mar 2020

Huibung, Park / President