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.

Product name	Brand name	Model name (Ref.no)
VABB(Vacuum-Assisted Breast Biopsy) System	Bexcore	BXS 100

Classification : Class IIa (Annex IX Rule 11, 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 , EN1041:2008, EN ISO 15223-1:2016, EN 60601-1:2006, EN60601-1-2:2007, EN 60601-1-6:2010 , EN ISO62304:2006/AC:2008, MEDDEV 2.7.1/Rev.4, MEDDEV 2.12.1/Rev.8, MEDDEV 2.12.2/Rev.2

Manufacturers Registered Name : MEDICAL PARK Co., Ltd.

EC Representative : JaviTech e.K
Sachsenhausener Straße 16, 65824 Schwalbach am Taunus, Germany
Tel: +49 6196 4021549

CE 1639

EC Certificate: KR19/81826310
GMDN Code No.: 36190[Stereotactic biopsy system, mammography]

Signature :

Date: 29 June 2020

Huibung, Park / President