Ref. No.: SPICA2022BA0157

APPOINTMENT OF UK RESPONSIBLE PERSONS AGREEMENT

We, Yongkang Beiqin industry & trade co., ltd
Address: No.18 Jintian Road, Wangxitian Natural Village, Long Qing Village, Xiangzhu Town, Yongkang City, Zhejiang Province, China
Tel: +8613645897889
E-mail: Ann@zjbeiqin.com
(hereinafter referred to as Party A)

And SPICA CONSULTING SERVICE LTD
Address: 41 DEVONSHIRE STREET GROUND FLOOR OFFICE 1, LONDON, UNITED KINGDOM W1G 7AB
Tel: +0044 20 3239 9866
E-mail: spica_uk@yahoo.com
(hereinafter referred to as Party B)

WHEREAS Party B offers regulatory services to medical device companies pursuant to the UK MDR 2002 (in the form in which they existed on 1 January 2021), requiring appointment of a UK Responsible Persons ; and, WHEREAS Party A wishes Party B to assist in the application for registration; NOW THEREFORE, for the mutual promises, covenants, and other good and valuable consideration further described hereinafter, the parties agree as follows:

For and on behalf
SPICA CONSU

1.Term:

1.1This Agreement is effective on the signature date of Party A and Party B, and is for a period of five year(s).

1.2 If Party A needs to renew this contract, it shall notify Party B in writing at least thirty (30) days before the real-time anniversary of the contract, any renewal hereof shall be at the then current Engagement Fee.

2.Party B

2.1 Party B acts on behalf of the outside-UK manufacturer to carry out specified tasks in relation to the Party A's obligations.This includes registering the party A's devices with the MHRA before the devices can be placed on the Great Britain market.

2.2 The responsibilities of Party B are set out in the UK MDR 2002 (as amended). In summary, in addition to the above registration requirements,Party should must:

2.2.1 ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by party A.

2.2.2 keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA.

2.2.3 in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device.

2.2.4 where party B have samples of the devices or access to the device, comply with any request from the MHRA to provide such samples or access to the device.

2.2.5 where party B have neither samples of the device nor access to the device, communicate to party A any request from the MHRA to provide such samples or access, and communicate to the MHRA whether the manufacturer intends to comply with that request.

2.2.6 cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices

2.2.7 immediately inform party A about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed.

2.2.8 if party A acts contrary to its obligations under these Regulations:

- Party B should terminate the legal relationship with party A; and
- inform the MHRA and, if applicable, the relevant Approved Body of that termination.

2.2.9 Party B

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Authorized

3.Party A

3.1 appoint party B as the UK Responsible Persons, and complete the registration within the grace period of MHRA.

3.2 ensure your products comply with the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) as your apply in Great Britain so that you can be registered with the MHRA.

3.3 To draw the declaration of conformity and technical documentation, and the copy shall be kept by Party B.

3.4 Party A shall retain Party B' s access to samples to comply with any request from the MHRA.

3.5 Party A is obliged to ensure that the information submitted is accurate and all information registered with the MHRA is accurate and up to date. In the event that the information submitted by the Party A is incorrect, Party A shall promptly make corrections and assume all liability arising from such situation.

3.6 inform Party B of your importer's intention to import a device, and provide party B with a list of device importers.

3.7 Party A will be fully responsible for the performance of its products and will hold Party A against any liability claim arising from the use of the products manufactured by Party A.

3.8 The name and address of the UK Responsible Person, where applicable, must be included on product labelling where the UKCA mark has been affixed. UK Responsible Person details do not need to be included on labelling for CE marked devices.

3.9The Agreement shall automatically terminate and expire when party A fails to pay the agreement fee in time.

4.The products covered by this agreement: Party B is the exclusive representative for all medical devices manufactured by Party A.

For and on behalf of
SPICA CONSULTING SERVICE LTD

5.Understood and Agreed to:

Party A: Yongkang Beimin industry & trade co., ltd

Signature:

Date: 2022.08.29

Party B: SPICA CONSULTING SERVICE LTD

Authorized Signature(s)

Signature: Creekon Yang.

Date: Sep. 1. 2022

VICE LTD

Yang.

nature(s)