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ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 003973 0002 Rev. 01

Manufacturer:

Beijing Konted Medical Technology Co., Ltd
Room 111, Building 3
No. 27 Yongwang Road
Daxing Biological Pharmaceutical Industry Base
Daxing District
102629 Beijing
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Pocket Ultrasound System.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: BJ18108021

Valid from: 2019-04-29
Valid until: 2023-08-05

Date, 2019-04-29

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
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(Devices in Class IIa, IIb or III)

No. G2 003973 0002 Rev. 01

Facility(ies):

Beijing Konted Medical Technology Co., Ltd
Room 111, Building 3, No. 27 Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, 102629 Beijing, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Beijing Konted Medical Technology Co., Ltd
Room 111, 1F, Building 3, No. 27, Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, 102629, Beijing,
P.R. China

19/07/2023

Confirmation Letter Reference: CLNB1639 – CN/BJS/258232

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer :

Beijing Konted Medical Technology Co., Ltd
Room 111, 1F, Building 3, No. 27, Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, 102629, Beijing,
P.R. China
SRN Number: CN-MF-000024104

Authorized representative:
SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel,
The Netherlands

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;

- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body SGS Belgium NV 1639,

pp [Haldun OGUZ]

Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

Devices covered by this letter:

Device name / Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	**MDD/AIMDD Certificate Reference(s)** of the devices under MDR application, and the NB Identification
Pocket Ultrasound System (Basic UDI-DI: 697387564C10SU)	Class IIa	N/A	Certificate No. G2 003973 0002 NB0123

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/07/19	Version 1	Initial issue