小超充电子制造（南通）有限公司
LITTLE DOCTOR ELECTRONIC (NANTONG) CO., LTD.
Economic and Technical Development Area
Nantong Jiangsu
P.R. of China
Tel.: +86 0513 85986718

27 April 2024

EU Representative
Little Doctor Europe Sp. z o. o.
Zawila Str. 57G 30-390
KRAKOW, POLAND

Dear Sirs,

CERTIFICATION BY TÜV SÜD PRODUCT SERVICE GMBH, REGULATION EU 2017/745 (MDR)

Herewith we declare that in accordance 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 our production was reported and subject to the certification process under new rules. Certificates are processed by TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation EU 2017/745 (MDR). In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2024, Notified Body: TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich, Germany will extend the validity of certificates before May 26, 2024 for another validity period, i.e. until December 31, 2028.

The MDR has been applicable since 26 May 2023. The transition period provided for in Article 120(3) will end on 26 May 2024. The IVDR has been applicable since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions. The extension of the transition period is complemented by an extension of the validity of certificates issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period.

Regulation EU 2017/745 is amended as follows:

(1) Article 120 is amended as follows:

Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into service until the following dates:
(a) 31 December 2027, for class III devices and for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
(b) 31 December 2028, for class IIb devices other than those covered by point (a), for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

In the same way as the current Article 120(3) MDR, the extended transition period applies only to 'legacy devices', i.e. those covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC before 26 May 2021.

Moreover, the application of the extended transition period is subject to several cumulative conditions, which are:

- the devices do not undergo significant changes in the design and intended purpose.
- the devices must continue to comply with Directive 90/385/EEC or Directive 93/42/EEC

Little Doctor Electronic (Nantong) Co., Ltd. has obtained a certificate from an authorized company GS1 and an ID for LDEN products (697368616):

1. Sphygmamonemter: 697368616ASMVU
2. Sphygmamonemter fittings: 697368616SMFXN
3. Stethoscope: 697368616STEY9
4. Stethoscope fittings: 697368616STFYB
5. DBPM: 697368616BPMVQ
6. DBPM fittings: 697368616BPFVA
7. Nebulizer: 697368616NEBVV
8. Nebulizer fittings: 697368616NEFW5
9. Irrigator: 697368616IRRXB
10. Irrigator fittings: 697368616IRFWK
11. Thermometers: 697368616THEXA

Sincerely,

LITTLE DOCTOR ELECTRONIC (NANNTONG) CO., LTD. 小通克电子制造（南通）有限公司 合同专用章

GAO JIAWEN
Director