深圳市科瑞康实业有限公司
Shenzhen Creative Industry Co., Ltd.
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Declaration for the Compliance with the REGULATION (EU)2023/607 For the Extension of the Validity of CE Certificate

In relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Name and address of the manufacturer:	**Shenzhen Creative Industry Co., Ltd.** **Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,** **Songbai Road, Xili Street, Nanshan District, 518110** **Shenzhen, PEOPLE'S REPUBLIC OF CHINA**
SRN (Manufucturer)	**CN-MF-000009430**
Name and address of Authorized Representative:	**Shanghai International Holding Corp. GmbH (Europe)** **Eiffestrasse 80, 20537 Hamburg GERMANY**
SRN (EU Authorised)	**DE-AR-000000001**
(EC)CERTIFICATE(S)	**G1 049076 0016 REV .03**
Medical Device:	**Patient Monitor, Vital Signs Monitor, Fingertip Oximeter, Handheld Pulse Oximeter, Wrist Oximeter, Easy ECG Monitor, Spot-Check Monitor, Sleep Screener, Multi Parameter Monitors for Capnography and Pulse Oximetry, Central Monitoring System** ***(For product details, such as Basic UDI-DI, see Table 1)***

We declare that the following criteria set out in REGULATION (EU) 2023/607 are met to make them eligible for the extension of the validity of the CE Certificate;

- QMS is in place in accordance with Article 10(9) MDR
- The contract for MDR conformity assessment was signed by Notified Body, TUV SUD on 20 Sept 2022 with contract number: GCN-GZ22153A04
- There are no significant changes in the design
- There is no change in the intended use of the devices
- The relevant device or devices shall not constitute an unacceptable risk to the health or safety of patients, users or other persons.
- The devices continue to comply with Directive 93/42/EEC MDD, as applicable.
- The MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices are met.
- Notified Body responsible for the surveillance of the devices.

We confirm that, our existing MDD Certificate which expires on 2024-05-26, will benefit from the MDR transition period until 31st December 2028, taking into consideration 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.

The required contract for MDR conformity assessment has already been signed by our Notified Body,TUV SUD.

We confirm that all the products that are listed in the above mentioned certificate will benefit from this transition.

Sincerely,

Zhang Xiang
Management Representative
Contact e-mail: zhangxiang@lepucloud.com

Shenzhen Creative Industry Co., Ltd.

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
Device 1 **Spot-Check Monitor** **69419006PC102017T**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 2 **Spot-Check Monitor** **69419006PC303018N**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 3 **Sleep Screener** **69419006AP2001AU**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 4 **Fingertip Oximeter** **69419006FOximeter0101 ZT**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	Individual Article number:	authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 5 **Fingertip Oximeter** **69419006FOximeter0102ZV**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 6 **Fingertip Oximeter** **69419006FOximeter010322**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 7 **Fingertip Oximeter** **69419006FOximeter010424**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 8 **Handheld Pulse Oximeter** **69419006HPOximeter0101HL**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A or ☐ Identification of the corresponding device under	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	MDD/AIMDD Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 9 **Wrist Oximeter** **69419006WOximeter0101PP**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 10 **Easy ECG Monitor** **69419006PC80BS01JB**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 11 **Patient Monitor** **69419006K15S01AK**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 12 **Patient Monitor** **69419006PC30000179**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted)	☒ N/A or ☐ Identification of the	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	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
	☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	corresponding device under MDD/AIMDD Individual Article number:	☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 13 **Patient Monitor** **69419006UP700001JR**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 14 **Vital Signs Monitor** **69419006PC90001A9**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 15 **Multi Parameter monitors for Capnography and Pulse oximetry** **69419006PC900B01CC**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123 or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Device 16 **Central Monitoring System** **69419006CMSPM0101DU**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ Class IIb / Class IIb	☒ N/A or	☒ Certification as follows: Certificate # G1 049076 0016 Rev. 03; NB# 0123

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	implantable (exempted) ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#