宝莱特 BIOLIGHT

Manufacturer Declaration for MDD CE Mark Extension Council Regulation (EU) 2023/706

Legal Manufacturer Name	Guangdong Biolight Meditech Co., Ltd.
Address	No.2 Innovation First Road, Technical Innovation Coast, Hi-tech Zone, Zhuhai 519085, Guangdong, P.R.China
Manufacturer SRN (if available)	CN-MF-000006333

EU REP Name	Shanghai International Holding Corp. GmbH (Europe)
Address EUDAMED SRN (if available)	Eiffestraβe 80, 20537 Hamburg GERMANY

Certificate(s) information and schedule Devices: See attached appendix.

With respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ('Directive Certificates") and their validity per Article 120.2 of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ('MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3 of the MDR:

We, as the Manufacturer confirm;

- The above-listed products and associated certificates meet the conditions for the legal extension of validity as required in Article 120.2 of the MDR.
- The Device(s) listed above are in compliance with the conditions listed in Article 120.3 of the MDR for continued placing on the market and putting into service.

Namely, the Directive Certificate covering the listed Devices:

- Has been issued after 25 May 2017
- Has not been withdrawn by 20 March 2023
- Was valid on 26 May 2021 and did not expire before 20 March 2023
- The Device(s) continue to comply with the MDD.
- The Device(s) have not been significantly changed in its design and intended purpose since 26 May 2021.
- The Device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.
- A quality management system in accordance with Article 10(9) MDR has been put in place.
- A formal application to the Notified Body in accordance with Section 4.3. first subparagraph of Annex VII, MDR for conformity assessment has been made for the Device(s) listed or their substitutes, and a corresponding written agreement in accordance with Section 4.3, second subparagraph of Annex VII has been signed by us and the Notified Body.
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with the MDR - as far as possible and required - is in place for the Device(s) listed.

Prepared By	**Approved By**
Name: Fenghua Cai	Name: Jin Liang Jin Liang
Position: Registration Specialist	Position: Chief Engineer
Signature: Fenghua Cai	Signature:
Date: 2024-02-20	Date: 2024-02-20

广东宝莱特医用科技股份有限公司
GUANGDONG BIOLIGHT MEDITECH CO.,LTD.
地址：珠海市高新区科技创新海岸创新一路2号 邮编：519085
Add：NO.2 Innovation First Road,Technical Innovation Coast,Hi-tech Zone,Zhuhai,P.R.China

宝莱特 BIOLIGHT

Appendix: Certificate(s) information and schedule Devices

Product Name(s)	Product Model	MDD Certificate(s)	Expiry Date on MDD Certificate	Extended Expiry Date	EU MDD Class	EU MDR Class
Patient monitor	M1000	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Vital Sign Monitor	V6	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Vital Sign Monitor	V9	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Patient monitor	M850	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Patient monitor	M860	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Patient monitor	M880	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Central Monitoring System	BioVision	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIb
Pulse oximeter	M70	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIa
Pulse oximeter	M70A	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIa
Pulse oximeter	M70C	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIa
Pulse oximeter	M800	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIb	Class IIa
Electronic Sphygmomanometer	WBP202	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIa	Class IIa
Electronic Sphygmomanometer	WBP302	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIa	Class IIa
Electrocardiograph	E30	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIa	Class IIa
Electrocardiograph	E65	No. G10499570033 Rev.02	2024-05-26	2028-12-31	Class IIa	Class IIa

广东宝莱特医用科技股份有限公司
GUANGDONG BIOLIGHT MEDITECH CO.,LTD.
地址：珠海市高新区科技创新海岸创新一路2号 邮编：519085
Add：NO.2 Innovation First Road,Technical Innovation Coast,Hi-tech Zone,Zhuhai,P.R.China
Tel：+86-756-3399935 Fax：+86-756-3399911 E-Mail:overseas@blt.com.cn www.blt.com.cn