# DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

*SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.*
*#16-1，JINHUI ROAD, JINSHA COMMUNITY, KENGZI SUB-DISTRICT, PINGSHAN NEW DISTRICT, 518122 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA*

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| MEDICAL DEVICE: | *PATIENT MONITOR*<br>*TYPE: IM 12, PM-900*<br>*GMDN CODE: 33586* |
| CLASSIFICATION - *ANNEX IX*: | *CLASS IIB, RULE 10* |
| *CONFORMITY ASSESSMENT ROUTE:* | *ANNEX VII.3* |

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

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| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY |
| *IDENTIFICATION NUMBER* | CE 0123 |
| (EC) CERTIFICATE(S): | *G1 17 0565758 004* |
| EC REP<br>EUROPEAN REPRESENTATIVE: | *SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)*<br>*Eiffestraße 80, 20537 HAMBURG, GERMANY* |

START OF CE-MARKING: *2012-08-02*

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| PLACE, DATE OF DECLARATION: | *SHENZHEN P.R.C., 2017-05-10* |
| SIGNATURE: | _____<br>*NAME: CHEN JUN*<br>*POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)* |

Digitally signed by Enrico Secu
Date: 2019.08.01 14:06:39 EEST
Reason: MoldSign Signature
Location: Moldova