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

MANUFACTURER: Beijing M&B Electronic Instruments, Co., Ltd

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MEDICAL DEVICE: Transcutaneous Jaundice Detector, MBJ20
UMDN CODE: 16-166
CLASSIFICATION - ANNEX IX: IIa, According To Rule 10
CONFORMITY ASSESSMENT ROUTE: II.3

WE HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

STANDARDS APPLIED:

EN 60601-1: 2006/AC:2013
EN 60601-1-2:2007/AC:2010
EN 60601-1-6:2010
EN ISO13485:2012
EN 980:2008
EN 1041:2008
EN ISO 14971:2012
EN 62304: 2006/AC:2008

NOTIFIED BODY: TÜV SÜD Product service GmbH
Ridlerstr 65, D-80339 München, Germany

*IDENTIFICATION NUMBER* CE 0123

(EC) CERTIFICATE(S): G1 067514 0018 Rev.00

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
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START OF CE-MARKING:
PLACE, DATE OF DECLARATION: JANUARY,2019

SIGNATURE: Runling Zhang

Name: Zhang Runling
Position: Management Responsibility