

EC Declaration of Conformity

F-QA-037 Rev.01 20160107

MANUFACTURER:

GLOBALCARE MEDICAL TECHNOLOGY CO., LTD

7th Building, 39 Middle Industrial Main Road, European Industrial Zone,

Xiaolan Town, 528415 Zhongshan City, Guangdong Province,

PEOPLE'S REPUBLIC OF CHINA

Product Category:

Blood Pressure Measuring Equipment

Product Code:

95254

Product Description:

BM28-MEDEL SENSE WAC ADAPT

Classification - Annex IX:

Class IIa. Rule 10

Conformity Assessment Route:

ANNEX V

We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 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. Globalcare Medical Technology CO., LTD. is exclusively responsible for this EC Declaration of Conformity.

Standards applied: see attached list

Notified Body:

TÜV SÜD Product Service Gmbh

Ridlerstr 65, D-80339 MÜNchen, Germany

Identification Number

0123

(EC) Certificate(s):

G2 088855 0011 Rev.00

EC REP

European Representative:

Donawa Lifescience Consulting Srl

Piazza Albania, 10

00153 Rome

Italy

Place, Date of Declaration:

Zhongshan, 2020-07-29

Signature:

Name: Lambert Zhao

Position: General Manager