beurer
GESUNDHEIT UND WOHLBEFINDEN

EC - DECLARATION OF CONFORMITY

Förderndes Mitglied der Deutschen Hochdruckliga

Förderndes Mitglied der Deutschen Diabetes Stiftung

No.:	BM28_CE_DoC, valid to 2019-07-02
Manufacturer:	Beurer GmbH
Address:	Söflinger Str. 218 89077 Ulm Germany

This declaration of conformity is issued under our sole responsibility.

UMDNS code and name:	16-174 Blood Pressure Monitor, electronic, manual
Category code and category:	04 Electrical and mechanical medical devices
Classification Rule/ Class:	Rule 10/ Class IIa
Product name:	BM28
Expiry Date:	2019-07-02

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation:

Directives_Date of last revision:	CD 93/42/EEC (MDD) amended with 2007/47/EEC_ 2010-03-21 CD 2011/65/EC (ROHS)_2011-06-08
Conformity assessment procedure:	Annex VII (Internal Production Control) in conjunction with Annex V (QA Production) of CD 93/42/EEC (MDD)
Relevant harmonised standards:	EN 60601-1: 2006 + A1: 2013 EN 60601-1-2: 2007 EN ISO 81060-1: 2012 EN 1060-3: 1997 + A2: 2009 EN 1060-4: 2004

The notified body mdc - medical device certification GmbH, located at Kriegerstr. 6, D-70191 Stuttgart, identification number 0483, issued in the course of conformity assessment procedure the following certificate:

Certificate No._issued on:	D1311700024_2015-12-08, valid to 2019-07-02
Signed for and on behalf of:	Beurer GmbH
Place, date of issue:	Ulm, 2017-12-20
Name, function and signature:	Werner Meternek, Director R&D / RA

i.V. Beurer GmbH Söflinger Str. 218 · 89077 Ulm

Digitally signed by Dicusar Vladimir
Date: 2020.09.04 17:20:47 EEST
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 067329 0010 Rev. 01

Manufacturer:

Wenzhou Kangju Medical Instrument Co., Ltd.
81 Liuzhai Luodong South Street, Yongzhong
325000 Wenzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):

Aneroid Sphygmomanometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: SH1852011

Valid from: 2018-12-17
Valid until: 2023-10-01

Date, 2018-12-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 067329 0010 Rev. 01

Facility(ies):

Wenzhou Kangju Medical Instrument Co., Ltd.
81 Liuzhai Luodong South Street, Yongzhong, 325000 Wenzhou,
Zhejiang, PEOPLE'S REPUBLIC OF CHINA

Nanjing Kangju Medical Instrument Co.,Ltd.
27 Huashan Road Gaochun Economy Zone, 211300 Nanjing,
Jiangsu, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

WENZHOU KANGJU MEDICAL INSTRUMENT CO., LTD.

81 Liuzhai Luodong South Street,Yongzhong 325000 Wenzhou, Zhejiang, China

EC DECLARATION OF CONFORMITY

The Wenzhou Kangju Medical Instrument Co. Ltd. , 81 Liuzhai Luodong South Street,Yongzhong 325000 Wenzhou, Zhejiang – People's Republic of China manufacturer of aneroid sphygmomanometer REF DM330,DM331,DM332,DM333,DM335,DM340,DM341,DM342,DM345,DM346,DM347,DM348,DM350,DM353,DM360 and DM365 declares that the above mentioned items are manufactured according to the 93/42/EEC directive on Medical devices for classe I with measuring function and it is certified with EC Certificare CE 0123 TUV Sud (EC Certificate No. G2M0673290010).

温州市康聚医疗仪表有限公司
WENZHOU KANGJU MEDICAL INSTRUMENT CO.,LTD.

Signature

OCT.8,2018

MORETTI S.p.A.
Via Bruxelles,3 - Meleto
52022 Cavriglia (Arezzo)

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P. IVA 00306090515
Meccanografico Ar005370
Reg. Imp. Arezzo 3932

R.E.A. 68869
Cap. Soc. € 1.000.000
C/C Postale 13682521
Reg.RAEE Nr.IT07121000010

DECLARATION OF CONFORMITY

CE

As per directive 93/42/EEC

Moretti S.p.A. declares under its sole responsibility that the product made and traded by Moretti S.p.A. and belonging to group

STETHOSCOPES

complies with the

European Directive on Medical devices 93/42/EEC
as modified by directive 2007/47/EEC

and the following international standards

EN ISO 14971:2009-EN 980:2009

For this purpose , Moretti S.p.A. guarantees and declared under its sole responsibility what follows:

1. The devices satisfy the essential requisites requested by the Annex I° directive 93/42/EEC as laid down by the Annex VII° of the above mentioned Directive.
2. The complete list of this range of medical devices is indicated on Annex I
3. The devices *ARE NOT MEASURING INSTRUMENTS*.
4. The devices *ARE NOT MADE FOR CLINICAL PROBES*.
5. The devices are traded with *NON STERILE BOX*.
6. The devices belong to class I°.
7. Moretti S.p.A. for at least 8 years from the last lot production, places technical documentation at relevant authorities in order to prove the conformity of 93/42/EEC directive,

Annex
Annex A – Medical devices list

11.01.19
MORETTI SpA
FILIPPO FABBRINI
CEO

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ANNEX A- MEDICAL DEVICES LIST

Products :

STETHOSCOPES

Codice	Description
DM130X	STETHOSCOPE ALUMINIMUM FLAT HEAD- ADULT TYPE
DM500X	STETHOSCOPE ROATTING ALUMINIMUM DOUBLE HEAD- ADULT
DM505X	STETHOSCOPE ROATTING ALUMINIMUM DOUBLE HEAD- PEDIATRIC
DM545X	STETHOSCOPE ANODIZED ZINC ANATOMIC HEAD- ADULT TYPE
DM530X	STETHOSCOPE ADULT TYPE
DM535X	STETHOSCOPE CARDIOLOGICAL ADULT TYPE
DM540X	STETHOSCOPE PEDIATRIC TYPE
DM561X	STETHOSCOPE RAPPAPORT TYPE