GTL 均威科技(深圳)有限公司
GRANDWAY TECHNOLOGY (SHENZHEN) LTD.

Document Number: 文件编号:	WI-KF-024	Version: 版本:	A	Revision: 版次:	34
Effective Date: 生效日期:	10-May-2022	Pages: 页数:	10		

CE Certificates
for
Digital Automatic Blood Pressure Monitor

Prepare by:	Eric Wong	Date:	10-May-2022
Check by:	Li Long Fei	Date:	10-May-2022
Approval by:	Patrick Chow	Date:	10-May-2022

Version 版本	Revision 版次	Revision Summary 修订内容摘要	Prepared by 修改人	Approved by 批准人	Effective Date 生效日期
A	0	Initial Release	---	Honson	10-Aug-2009
A	1	Update Certificate & Model	Eric	Honson	10-Sep-2009
A	2	Update Certificate & Model	Eric	Patrick	10-Oct-2010
A	3	Update Certificate & Model	Eric	Patrick	10-Nov-2011
A	4	Update Certificate & Model	Eric	Patrick	02-Dec-2011
A	5	Update Certificate & Model	Eric	Patrick	02-Apr-2012
A	6	Revised Certificate & Model	Eric	Patrick	23-Jul-2012
A	7	Revised Certificate & Model	Eric	Patrick	10-Oct-2012
A	8	Revised Certificate & Model	Eric	Patrick	17-Oct-2013
A	9	Update Certificate & Model	Eric	Patrick	16-Dec-2013
A	10	Update Certificate & Model	Eric	Patrick	07-Apr-2014
A	11	Update Certificate & Model	Eric	Patrick	10-Dec-2014
A	12	Update Certificate & Model	Eric	Patrick	08-Jan-2015
A	13	Update Certificate & Model	Eric	Patrick	22-Apr-2015
A	14	Update Certificate & Model	Eric	Patrick	04-May-2015
A	15	Update Certificate & Model	Eric	Patrick	01-Jun-2015
A	16	Update Certificate & Model	Eric	Patrick	15-Jul-2015
A	17	Update Certificate & Model	Eric	Patrick	23-Sep-2015
A	18	Update Certificate & Model	Eric	Patrick	08-Jan-2016
A	19	Update Certificate & Model	Eric	Patrick	27-Jul-2016
A	20	Update Certificate & Model	Eric	Patrick	20-Oct-2016
A	21	Update Certificate & Model	Eric	Patrick	28-Jun-2017
A	22	Update Certificate & Model	Eric	Patrick	21-Dec-2017
A	23	Update Certificate & Model	Eric	Patrick	19-Apr-2018
A	24	Update EC and QMS Cert.	Eric	Patrick	05-Sep-2018
A	25	Update Certificate & Model	Eric	Patrick	31-Oct-2018
A	26	Update Certificate & Model	Eric	Patrick	19-Jul-2019
A	27	Update Certificate & Model	Eric	Patrick	29-Nov-2019
A	28	Update Certificate & Model	Eric	Patrick	29-May-2020

A	29	Update Certificate No.	Eric	Patrick	18-Aug-2020
A	30	Update Certificate & Model	Eric	Patrick	20-Oct-2020
A	31	Update Certificate & Model	Eric	Patrick	18-May-2021
A	32	Added MD code	Eric	Patrick	11-Jun-2021
A	33	Update ISO 13485 Certificate	Eric	Patrick	02-Jul-2021
A	34	Correct typo & update sold date	Eric	Patrick	10-May-2022

For medical device, the product must be fulfilling the Directive Essential Requirements before adding CE Mark. On-Site Audit for certification body can be proved the factory quality system which meet this Directive Essential Requirements and the capacity to meet this Requirements continuously for the future, our quality system will keep check the production processing by relative documentation.

So, the medical device manufacturer must build up the quality system under ISO13485 regulation and get the Medical CE keep check by certification body.

The two attached certificates show the successful for our quality system under ISO13485:2016 regulation and pass the Medical CE (CE 0123) for Digital Automatic Blood Pressure Monitor by certification body. The control list includes all the model numbers which fulfil the regulation for production.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 061379 0027 Rev. 01

Holder of Certificate: **Grandway Technology (Shenzhen) Limited**
No. 5, the Second Industrial Zone
Zhukeng Community, Longtian Street
Pingshan District
518118 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Electronic Blood Pressure Meters**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 061379 0027 Rev. 01

Report No.: GZ2114701

Valid from: 2021-08-01
Valid until: 2024-07-31

Date, 2021-06-30

Christoph Dicks
Head of Certification/Notified Body

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 061379 0027 Rev. 01

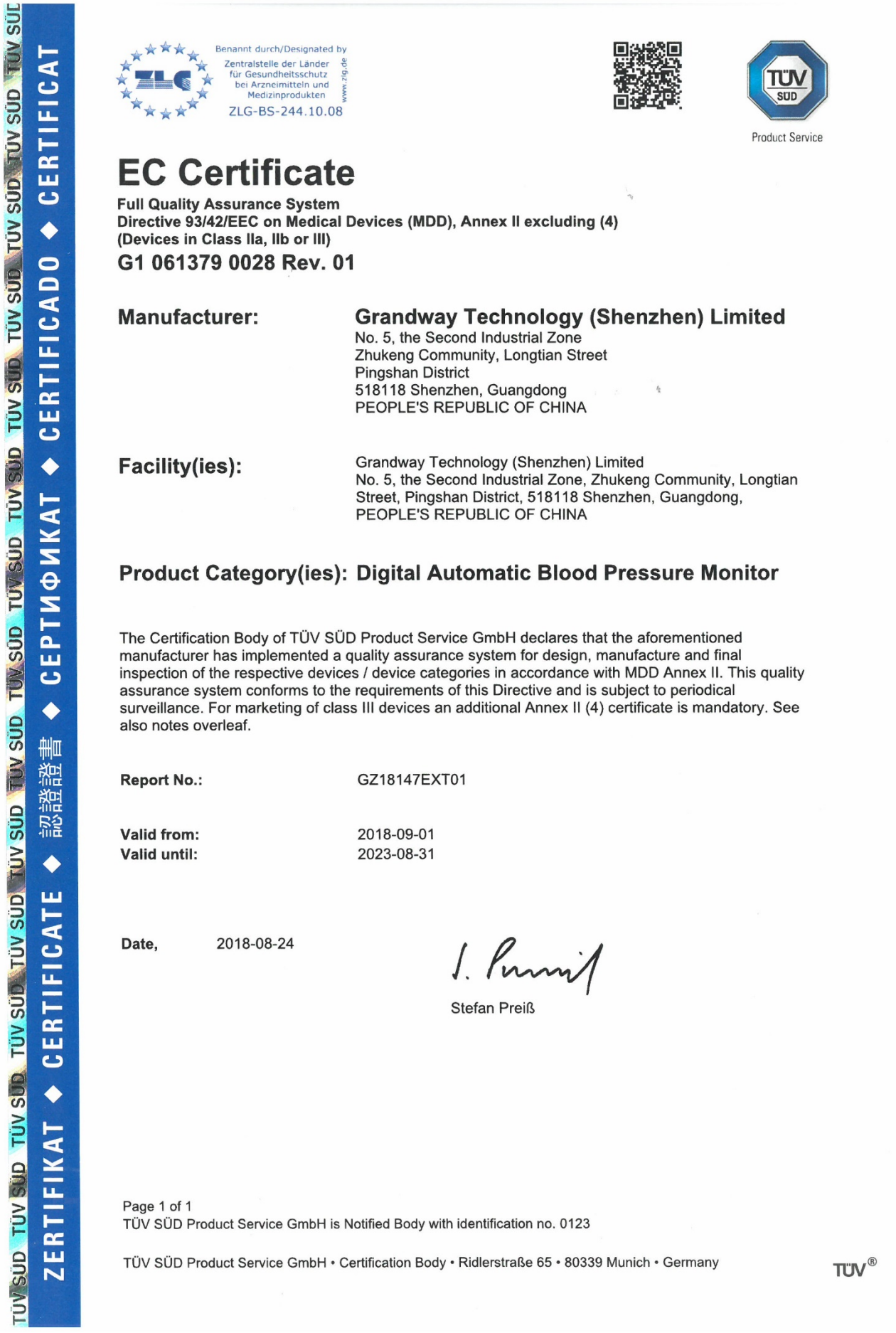
Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Grandway Technology (Shenzhen) Limited
No. 5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, 518118 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Electronic Blood Pressure Meters



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

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

G1 061379 0028 Rev. 01

Manufacturer:

Grandway Technology (Shenzhen) Limited
No. 5, the Second Industrial Zone
Zhukeng Community, Longtian Street
Pingshan District
518118 Shenzhen, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Grandway Technology (Shenzhen) Limited
No. 5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, 518118 Shenzhen, Guangdong,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Digital Automatic Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: GZ18147EXT01

Valid from: 2018-09-01
Valid until: 2023-08-31

Date, 2018-08-24

Stefan Preiß

Page 1 of 1
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®

A4 / 07.17

CE-marked products list

NO.: 2022190001

NO.	NAME	Model	Classification	Rule	UMDNS Codes	MD Code	CERT.NO.	OEM Information			Sold date at first time with own CE mark
								OEM NAME	NB Name	CERT.NO.	
1	Digital Automatic Blood Pressure Monitor	MD0100	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Nov of 2008
2	Digital Automatic Blood Pressure Monitor	MD0300	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	No
3	Digital Automatic Blood Pressure Monitor	MD0310	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	March of 2010
4	Digital Automatic Blood Pressure Monitor	MD0900	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	March of 2010
5	Digital Automatic Wrist Blood Pressure Monitor	MD0200, MD0210, MD0220, MD0230, MD0240, MD0250, MD0260, MD0270, MD0280	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	March of 2010
6	Digital Automatic Wrist Blood Pressure Monitor	MD1000	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	No
7	Digital Automatic Blood Pressure Monitor	MD0320, MD0330, MD0340, MD0350, MD0360	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
8	Digital Automatic Blood Pressure Monitor	MD0600, MD0610, MD0620, MD0630, MD0640, MD0650, MD0660, MD0670	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
9	Digital Automatic Wrist Blood Pressure Monitor	MD0700, MD0710, MD0720, MD0730, MD0740, MD0750, MD0760, MD0770, MD0780, MD0790	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
10	Digital Automatic Wrist Blood Pressure Monitor	MD1010	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	No
11	Digital Automatic Blood Pressure Monitor	MD1100, MD1110, MD1120, MD1130, MD1140, MD1150, MD1160, MD1170, MD1180	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
12	Digital Automatic Wrist Blood Pressure Monitor	MD1200, MD1210, MD1220	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
13	Digital Automatic Blood Pressure Monitor	MD1300, MD1310, MD1320, MD1340	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
14	Digital Automatic Wrist Blood Pressure Monitor	MD1500, MD1520, MD1530, MD1560 MD1590	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2011
15	Digital Automatic Wrist Blood Pressure Monitor	MD1700 (SBC42), MD1710 (SBC42L)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2011
16	Digital Automatic Blood Pressure Monitor	MD1600 (SBM52)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2011
17	Digital Automatic Wrist Blood Pressure Monitor	New MD1700 (New SBC42)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2011
18	Digital Automatic Blood Pressure Monitor	MD1900 (SBM42)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2013

CE-marked products list

NO.: 2022190001

NO.	NAME	Model	Classification	Rule	UMDNS Codes	MD Code	CERT.NO.	OEM Information			Sold date at first time with own CE mark
								OEM NAME	NB Name	CERT.NO.	
19	Digital Automatic Blood Pressure Monitor	MD1800, MD1810, MD1820, MD1830, MD1840, MD1850, MD1860, MD1870	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
20	Digital Automatic Blood Pressure Monitor	MD1801, MD1811, MD1821, MD1831, MD1841, MD1851, MD1861, MD1871	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
21	Digital Automatic Blood Pressure Monitor	MD2000, MD2010, MD2020, MD2030, MD2040, MD2050, MD2060, MD2070, MD2080, MD2090,	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
22	Digital Automatic Blood Pressure Monitor	MD2001, MD2011, MD2021, MD2031, MD2041, MD2051, MD2061, MD2071	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
23	Digital Automatic Wrist Blood Pressure Monitor	MD2220,MD2222,MD2223	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
24	Digital Automatic Wrist Blood Pressure Monitor	MD2230,MD2231,MD2232	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2013
25	Digital Automatic Blood Pressure Monitor	MD2300 (BM45)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Oct of 2013
26	Digital Automatic Wrist Blood Pressure Monitor	MD2400 (SBC25-1)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Sep of 2013
27	Digital Automatic Blood Pressure Monitor	MD1910 (SBM44)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2013
28	Digital Automatic Wrist Blood Pressure Monitor	MD2200, MD2210	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Feb of 2015
29	Digital Automatic Blood Pressure Monitor	MD2800, MD2810	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Apr of 2014
30	Digital Automatic Blood Pressure Monitor	MD3800	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jul of 2014
31	Digital Automatic Blood Pressure Monitor	MD3300, MD3310, MD3320	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jul of 2014
32	Digital Automatic Wrist Blood Pressure Monitor	MD3400	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2014
33	Digital Automatic Wrist Blood Pressure Monitor	MD3500	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Nov of 2014
34	Digital Automatic Blood Pressure Monitor	MD2500, MD2510, MD2520, MD2530, MD2540, MD2550, MD2560, MD2570, MD2580, MD2590, MD25A0, MD25B0	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	May of 2016
35	Digital Automatic Blood Pressure Monitor	MD2600, MD2610, MD2620, MD2630, MD2640, MD2650, MD2660, MD2670, MD2680, MD2690, MD26A0, MD26B0	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jun of 2016

CE-marked products list

NO.: 2022190001

NO.	NAME	Model	Classification	Rule	UMDNS Codes	MD Code	CERT.NO.	OEM Information			Sold date at first time with own CE mark
								OEM NAME	NB Name	CERT.NO.	
36	Digital Automatic Blood Pressure Monitor	MD4000	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jan of 2015
37	Digital Automatic Wrist Blood Pressure Monitor	MD3900	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Feb of 2015
38	Digital Automatic Blood Pressure Monitor	MD3000, MD3010, MD3020, MD3030, MD3040, MD3050, MD3001, MD3011, MD3021, MD3031, MD3041, MD3051	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	May of 2016
39	Digital Automatic Blood Pressure Monitor	MD3100, MD3110, MD3120, MD3130, MD3140, MD3150, MD3101, MD3111, MD3121, MD3131, MD3141, MD3151	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2016
40	Digital Automatic Wrist Blood Pressure Monitor	MD3200	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jul of 2014
41	Digital Automatic Blood Pressure Monitor	MD3600	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Apr of 2015
42	Digital Automatic Blood Pressure Monitor	MD4200	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2015
43	Digital Automatic Wrist Blood Pressure Monitor	MD4300	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Dec of 2015
44	Digital Automatic Wrist Blood Pressure Monitor	MD4600	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jun of 2016
45	Digital Automatic Blood Pressure Monitor	MD4100, MD4110, MD4120, MD4130, MD4140, MD4150, MD4160, MD4170, MD4180, MD4190, MD41A0, MD41W0 MD41W1	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Sep of 2018
46	Digital Automatic Blood Pressure Monitor	MD5100	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	May of 2017
47	Digital Automatic Wrist Blood Pressure Monitor	MD5000, MD5020, MD5090, MD5001, MD5021, MD5091	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2017
48	Digital Automatic Blood Pressure Monitor	MD4700, MD4710, MD4720, MD4730, MD4740, MD4750, MD4760, MD4770, MD4780, MD4790, MD47A0, MD47B0	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jun of 2018

CE-marked products list

NO.: 2022190001

NO.	NAME	Model	Classification	Rule	UMDNS Codes	MD Code	CERT.NO.	OEM Information			Sold date at first time with own CE mark
								OEM NAME	NB Name	CERT.NO.	
49	Digital Automatic Wrist Blood Pressure Monitor	MD5200, MD5210, MD5220, MD5230, MD5240, MD5250	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Aug of 2019
50	Digital Automatic Blood Pressure Monitor	MD5400, MD5401, MD5450, MD5451, MD5470, MD5471	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	April of 2021
51	Digital Automatic Wrist Blood Pressure Monitor	MD5300, MD5330, MD5350, MD5370, MD5390, MD53B0, MD5301, MD5331, MD5351, MD5371, MD5391, MD53B1)	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jun of 2019
52	Digital Automatic Blood Pressure Monitor	MD5500, MD5510, MD5520, MD5530, MD5540, MD5550, MD5560, MD5570, MD5580, MD5590, MD55A0, MD55B0, MD5601, MD5611, MD5621, MD5631, MD5641, MD5651, MD5661, MD5671, MD5681, MD5691, MD56A1, MD56B1	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jul of 2019
53	Digital Automatic Blood Pressure Monitor	MD6000	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jan of 2021
54	Digital Automatic Blood Pressure Monitor	MD5900, MD5910, MD5920, MD5930, MD5940, MD5950, MD5960, MD5970, MD5980, MD5990	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	April of 2021

Author: Eric Wong
Date: 10-May-22

Approval Patrick Chow
Date: 10-May-22

CE-marked products list

NO.: 2022190001

NO.	NAME	Model	Classification	Rule	UMDNS Codes	MD Code	CERT.NO.	OEM Information			Sold date at first time with own CE mark
								OEM NAME	NB Name	CERT.NO.	
54	Digital Automatic Blood Pressure Monitor	MD6000	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	Jan of 2021
55	Digital Automatic Blood Pressure Monitor	MD5900, MD5910, MD5920, MD5930, MD5940, MD5950, MD5960, MD5970, MD5980, MD5990	Type II a	Rule 10	16173	MD 1302	G1 061379 0028 Rev 0.1	N.A	N.A	N.A	April of 2021

Author: Eric Wong
Date: 10-May-22

Approval Patrick Chow
Date: 10-May-22