

# VDE Prüf- und Zertifizierungsinstitut

VDE VERBAND DER ELEKTROTECHNIK  
ELEKTRONIK INFORMATIONSTECHNIK e.V.

## Certificate

### Declaration of conformity with Annex II Section 3.2 of Directive 93/42/EEC concerning medical devices

Holder of the certificate	Rossmax International Ltd. 12F., No. 189, Kang Chien Rd. Nei Hu District, TAIPEI 114 TAIWAN
Production facilities:	Rossmax International Ltd. 12F., No. 189, Kang Chien Rd., Nei Hu District, TAIPEI 114, TAIWAN  Rossmax (Shanghai) Incorporated Ltd. No. 6018 Huyi Road, Waigang, Jiading District, SHANGHAI 201806, CHINA
Product categories:	Design, manufacturing and distribution of non invasive blood pressure measuring device
Products covered by this Certificate:	See appendix no. 1
Certificate number:	0366/MDD/2045000-II
Valid until:	2012-04-18
Auditor report and further documents filed under record no.:	2045000-9100-0001/83682

The certificate was issued according to Annex II Section 3.2 of the EC Directive 93/42/EEC concerning medical devices.

This certificate relates to the audited and monitored quality assurance system and is the basis for the EC Declaration of Conformity required for marketing. This certificate is a permission to label the medical device with the CE Marking and designated number 0366 as long as the conformity audit and inspection procedure required by the EC directive will be completely fulfilled.

D-63069 Offenbach am Main, 2007-04-19  
Merianstraße 28

VDE Prüf- und Zertifizierungsinstitut  
VDE Testing and Certification Institute  
Zertifizierungstelle / Certification



The VDE Testing and Certification Institute is a notified body with the EC reference no. 0366 and accredited by the "Zentralstelle der Länder für Sicherheitstechnik" (ZLS)



Appendix no. 1

To the certificate 0366/MDD/2045000-II dated 2007-04-19  
according to Annex II 93/42/EEC

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Holder of the certificate: Rossmax International Ltd.  
12F., No. 189, Kang Chien Rd.  
Nei Hu District, TAIPEI 114,  
TAIWAN

Product categories: Design, manufacturing and distribution of  
non invasive blood pressure measuring device

Products covered by this certificate: A40; A43; A46; AC700k(PC/CA); AC701k(PC/CA); AD700k(PC/CA); AD701k(PC/CA); AF701fCA; AG701fCA; AI95CA; AK150f(CA), AK151f(CA); AL401fCA; AM941fCA; AJ700f(PC/CA); AJ701f(PC/CA); AB700f(PC/CA); AB701f(PC/CA); AR951; B150; B350; B400; BA350PC; BA701CA; BC351; BC351CA; BC701; BC701CA; BD350(PC/CA); BD351(PC/CA); BE701CA; BD701CA; BH701CA; BI701(PC/CA); BL700(PC/CA); BL701(PC/CA); BPM600T; C380; CardioCare 1000i; CardioPro 1000i; CardioPro 3000i; D150; D400; **D400(CA); DM430;** DM436; DM437; DM438; E350 PC; G101; G150; G350; G380; G400; H150; H350CA; H400; J400; J400CA; **J400(PC/CA);** J401; K150, K350; K380; K400; **K400(CA);** Life Choice 150; Life Choice 400; Life Choice 400PC; Mandaus II; M43; M44; M46; MA 90, MA 350f, MA800i MB303, MB305, MB306, MB306f, MB307, MB321; MediCare 10; MediCare 60; MediCare 100f; MediCare 101; MediCare 200i; MediCare 300i; MediGuard 70, MediGuard 400iPC, MediGuard 500i; MediPro 10; MediPro 60; MediPro 100i; MediPro 100f; MediPro 200i; MediPro 300i; Medi Source 60; Medi Source 150i; ME150f, ME350f; ME700f(PC/CA); ME701f(PC/CA); ME700i PC, MF40; MF150f; MF400f; MF400iPC, MF400f PC, MF400i; MG40; MG150f; MG400i; MG400f; MH150fCA; MH901iCA; **MI350f(PC/CA); MI351f(PC/CA);** MI821fCA; MJ90; MJ90CA, MJ150f; MJ700f(PC/CA); MJ701f(PC/CA); MJ701iCA, ML350f; ML600i, ML600iPC; MN95CA; MN601fCA; MN901fCA; MO701fCA, MO701iCA; MO701kCA; MP150f; MP400i, MQ350f, MQ350fPC; MQ350iPC; MQ700iPC; MR250f; MR800fCA; MR801fCA; MR900f(PC/CA), MR901f(PC/CA), MH900f(PC/CA), MH901f(PC/CA); MS400i; MS150f; MS400f; MT60; MT150f; MT400i; MV601fCA, MV700f(PC/CA); MV701f(PC/CA); MV701i; MV801i; MV800iPC; MV901iCA; MW700k(PC/CA); MW701k(PC/CA); MW701fCA; MW820f(PC/CA); MW821f(PC/CA); MW941k(PC/CA); MX821iCA, MZ701fCA; O400; **O400(CA);** P400; T400(PC/CA); T401(PC/CA); Philips HF-306; Philips HF-318; Philips HF-319; Philips HF-321; PRAXI29130; Q150; Q400; Q401; R43; **RC5F;** RM-3000; RM-4000; RM-4100; RM-4200; S380; T400; V150; V701CA; X150, X400; Y701, Y701CA; Z43; Z44; Z46; 4606; 4607; 4608

VDE file no.: 2045000-9100-0001/125020

VDE Prüf- und Zertifizierungsinstitut GmbH  
VDE Testing and Certification Institute  
Zertifizierungsstelle / Certification



D-63069 Offenbach/Main, Merianstraße 28

Datum: 2009-10-29

Please disregard all previous appendices