

EC Declaration of Conformity

We, **Kaz Europe Sàrl**, Place Chauderon 18, 1003 Lausanne, Switzerland declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the EC Directive(s):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Name

Braun ExactFit™ 3 / ExactFit™ 5 Blood Pressure Monitor BP6000 series

Type or model

BP6000MRCEME
BP6000MRWE
BP6100PHEMEA
BP6100CN
BP6100AU
BP6200PHEMEA
BP6200AP
BP6200KO
BP6200CN
BP6200AU
BUA610LAD1
BUA610LA
BUA620LAD1
BUA620LA

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Standards Applied:

Standard Reference	Edition	Title
EN 1060-1:1995 /A2:2009	1995	Non-invasive sphygmomanometers — Part 1: General requirements.
EN 1060-3: 1997 /A2:2009	1997	Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.
EN 1060-4	2004	Non-invasive sphygmomanometers — Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.
EN 60601-1:2006/AC:2010	2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN ISO 14971	2012	Medical devices — Application of risk management to medical devices.
EN ISO 10993-1	2009	Biological evaluation of medical devices — Part 1: Evaluation and testing.
EN 60601-1-2	2007	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
EN 60601-1-11	2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN 62304/AC:2008	2006	Medical device software – Software life-cycle processes.
EN 60601-1-6	2007	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN 62366	2008	Medical devices — Application of usability engineering to medical devices.
DIRECTIVE 2011/65/EU	2011	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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Conformity assessment procedure:

Device Classification

IIa (Annex IX rule 10)

Annex

V

UMDNS

13-106

The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Place Chauderon 18, CH-1003 Lausanne, Switzerland

Notified body: DQS Medizinprodukte GmbH, August Schanz Str. 21, D-60433, Frankfurt, Germany (registration number: 0297)

Authorized Representative in Turkey: Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.

Address:

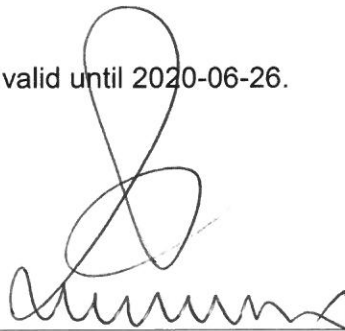
Ortaklar Cad. Bahçeler Sok.
18 İş Merkezi K:4 D:7 Mecidiyeköy
34394 İstanbul
Turkey

Tel:

+90 212 216 2950

This declaration of conformity is valid until 2020-06-26.

Roelof Zeijpveld



Lausanne

02 August 2017

General Manager

Legally binding signature

Place

Date

Company Stamp:

Kaz Europe Sàrl
(formerly Kaz Europe SA)
Place Chauderon 18
CH-1003 Lausanne
T. +41 21 644 01 10
F. +41 21 644 01 11