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	**Type or model**
Braun ExactFit™ 3 / ExactFit™ 5 Blood Pressure Monitor BP6000 series	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	Annex	UMDNS
IIa (Annex IX rule 10)	V	13-106

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

Roelof Zeijpveld		Lausanne	02 August 2017
General Manager	Legally binding signature	Place	Date

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