

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 European Directive:

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

Name

Model number

Braun VitalScan™ 1 Blood Pressure Monitor BBP2000

**BBP2000CEME
BBP2000WE
BPW200LA
BPW200LAD1
BPW200AR**

Braun VitalScan™ 3 Blood Pressure Monitor BBP2200

**BBP2200CEME
BBP2200WE
BPW220LA
BPW220LAD1
BPW220AR**

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Standards Applied:

Standard Reference	Edition	Title
EN 1060-1	1995	Non-invasive sphygmomanometers — Part 1: General requirements.
EN 1060-3 + 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 80601-2-30	2009	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
EN 60601-1 / 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 62304	2006	Medical device software – Software life-cycle processes.
EN 60601-1-6 / AC:2010	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.
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 980	2008	Symbols for use in labeling of medical devices.
EN 1041	2008	Information supplied by the manufacturer of medical devices.

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Conformity assessment procedure:

Device Classification

IIa (Annex IX rule 10)

Annex

V

UMDNS

16-174

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)

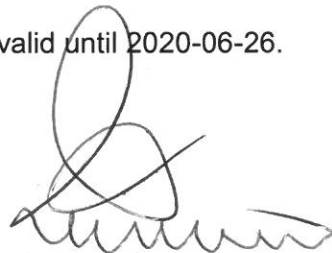
Authorized Representative in Turkey: Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.

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 February 2016

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

