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 ActivScan 9 Blood Pressure Monitor BUA7200	BUA7200WE BUA7200CEME

EC Declaration of Conformity

Standards Applied:

Standard Reference	Edition	Title
BS EN ISO 81060-2	2014	Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
EN 60601-1:2006 / A1:2013	2006	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2	2014	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
IEC 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 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 60601-1-11	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.

EC Declaration of Conformity

Conformity assessment procedure:

Device Classification	Annex	UMDNS
IIa (Annex IX rule 10)	V	16-174

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

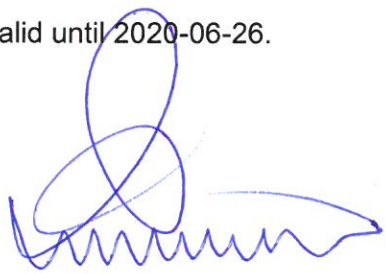
Notified body: DQS Medizinprodukte GmbH, August Schanz Str. 21, D-60433, Frankfurt, Germany (registration number: 0297)

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	09 April 2018
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