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 below Directive(s):

- **MDD - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**
- **RED - Directive 2014/53/EU of 16 April 2014 concerning radio equipment**
- **RoHS - 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**

Name	**Type or model**
Braun ExactFit™ 5 Connect Blood Pressure Monitor	BUA6350EU

Standards Applied:

Standard Reference	Edition	Title
EN ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971	2019	Medical devices — Application of risk management to medical devices.
EN 60601-1	2006 + A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-11	2015	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 IEC 80601-2-30	2019	Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
EN 60601-1-2	2015	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
EN 62304	2006 + A1:2008	Medical device software – Software life-cycle processes.
EN 62366-1	2015	Medical devices — Application of usability engineering to medical devices.
EN 60601-1-6	2010	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN ISO 10993-1	2009 + AC:2010	Biological evaluation of medical devices — Part 1: Evaluation and testing.
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN ISO 15223-1	2016	Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1 – General requirements
EN 1041	2008 + A1:2013	Information supplied by the manufacturer of medical devices
EN 80601-2-30	2010 + A1:2015	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN ISO 14155	2011 + AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 81060-2	2014	Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type
ETSI EN 300 328	V2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
ETSI EN 301 489-1	V2.2.3	EN 301 489-1
ETSI EN 301 489-17	V3.2.4	EN 301 489-17
EN 62479 EN 50663	2010 2017	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

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

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Additional information:

For Medical Device Directive 93/42/EC	
Regulatory class (MDD, Annex IX):	class IIa (Annex IX rule 10)
Conformity assessment procedure:	Annex V
GMDN	45617
UMDNS	16-174
Notified Body	DQS Medizinprodukte GmbH August Schanz Str. 21 D-60433 Frankfurt, Germany Registration number: 0297
EC Certificate	381008 MR5
EN ISO 13485 Certificate	381008 MP2016

For Radio Equipment Directive 2014/53/EU	
Conformity assessment procedure:	Annex III – Modules B and C – EU Type Examination + Conformity to type based on Internal Production Control
Notified Body for EU Type Examination	CTI-CEM International ltd 200 Greenogue Business Park Grants Lane, Rathcoole, Co. Dublin, Ireland Registration number: 1942
EU Type Examination Certificate	C-353-44-0210-22-01

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This declaration of conformity is valid until May 26, 2024.

Michael Burke		Lausanne	March 04, 2022
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp: Helen of Troy

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