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**
- **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 No Touch + Forehead Thermometer (also named as Braun Touchless + Forehead Thermometer) NTF3000 series	NTF3000WE NTF3000EE NTF 3000 NTF3000AP NTF3000KO NTF3000AU NTF3000CN NTF3000JP NTF3000LA NTF3000AR

Standards Applied:

Standard Reference	Edition	Title
EN 60601-1	2006 +A1:2013 +A12:2014	Medical electrical equipment - Part 1: General requirements for safety and essential performance.
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 60601-1-6	2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
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	2006/AC:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 12470-5	2003	Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device)
EN ISO 14971	2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1	2016	Graphical symbols for use in the labelling of medical devices
ASTM E1965-98	2003	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

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

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	17888
UMDNS	14-036
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

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

Michael Burke		Lausanne	December 8, 2021
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

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