Kaz Europe Sàrl
Place Chauderon 18
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EU 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 Regulation(s) and Directive(s):

- **MDR – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices**

Name / Registered Trade name / Registered trademark	Reference(s)
Braun Manual Nasal Aspirator filters	BNF020EU

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 62366-1	2015	Medical devices — Application of usability engineering to medical devices.
EN 60601-1-6	2010 + A1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
ISO 10993-1	2018	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 ISO 14155	2011 + AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice

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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 Regulation 2017/745	
Regulatory class (MDR, Annex VIII):	class I (Annex VIII rule 1)
Conformity assessment procedure:	Annex IV
Basic UDI-DI	76307593BNA050EX
Global /universal nomenclature	GMDN 41826 and UMDNS 10-216
EN ISO 13485 Certificate	381008 MP2016

Authorized Representative in Europe:	Authorized Representative in Turkey
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Revision	Change Description	Approval date
00	Initial document	See below

This declaration of conformity is valid from July 28, 2021.

Michael Burke		Lausanne	July 28, 2021
General Manager EMEA	Legally binding signature	Place	Date

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