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**

Name	**Type or model**
ThermoScan Hygiene cap	**Type or model** LF40EULA01 LF20, LF40 (double pack) LF20, LF40 (double pack)

Standards Applied:

Standard Reference	Edition	Title
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
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
EN 1041	2008	Information supplied by the manufacturer with medical devices

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 5)
Conformity assessment procedure:	Annex V
GMDN	13116
UMDNS	16-576
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 08, 2021
General Manager EMEA	Legally binding signature	Place	Date

Company Stamp:

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