

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
Lens Filter / Protection Cap for IRT thermometer Type LF40 (double pack)	LF40EULA01 LF20 (part of LF40)

Standards Applied:

Reference Number	Title	Date of issue
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing	2009
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
EN ISO 15223-1	Graphical symbols for use in the labelling of medical devices	2016
EN 1041	Information supplied by the manufacturer with medical devices	2008

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Conformity assessment procedure:

Device Classification	Annex	UMDNS	GMDN
Ila (Annex IX rule 5)	V	16-576	13116

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)

This declaration of conformity is valid until 2023-06-26.


Roelof Zeijpveld

p.o. Maria Feyjalka
General Manager

Legally binding signature

Lausanne 06 Dec 2018

Place

Date

Company Stamp: