FUJIREBIO INC.
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https://www.fujirebio.com/en/

Declaration of Conformity

MANUFACTURER:	Fujirebio Inc. 1-8-1 Akasaka, Minato-ku, Tokyo 107-0052, JAPAN
PRODUCT:	**Lumipulse 25-OH Vitamin D** Lumipulse G 25-OH Vitamin D Immunoreaction Cartridges Lumipulse G 25-OH Vitamin D Calibrators
Risk classification:	B

We herewith declare that the Standards listed below are applied for this product::

(1)	ISO 13485: 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
(2)	EN 13612: 2002/AC: 2002	Performance evaluation of in vitro diagnostic medical devices
(3)	ISO 14971: 2019	Application of risk management to Medical Devices
(4)	EN ISO 18113-1:2011	Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
(5)	EN ISO 18113-2:2011	Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
(6)	EN ISO 15223-1:2021	Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
(7)	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
(8)	EN ISO 17511:2003	Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials
(9)	EN ISO 23640: 2015	Evaluation of stability of in vitro diagnostic reagents

On behalf of Manufacturer,

SIGNATURE: Shuichi Kishimoto DATE: 2023-11-15

Shuichi Kishimoto
Marketing Supervisor-General
Fujirebio Inc.