

EU DECLARATION OF CONFORMITY

Manufacturer	Eurospital S.p.A.
Site Address	Via Flavia 122, 34147 Trieste - ITALY
Single Registration Number (SRN)	IT-MF-000028468
In Vitro Diagnostic Medical Devices:	See list of references annexed in this Declaration
Risk classification:	Class A rule 5b of Annex VIII of EU Regulation 2017/746
BASIC UDI-DI:	802816920AW01020608032G

The Company Eurospital S.p.A. declares that the In Vitro Diagnostic Medical Devices, listed here below, meet all pertinent Requirements of EU Regulation 2017/746 related to the In Vitro Diagnostic Medical Devices and comply with the applicable laws.

The Technical Documentation are kept updated by the Manufacturer and are available for Competent Authorities, as prescribed by the EU Regulation 2017/746.

Eurospital S.p.A. developed a procedure for post-marketing surveillance according to the EU Regulation 2017/746 requirements.

A Declaration of Conformity related to every single batch placed on the market is reported on batch documentation in a synthetic mode.

Eurospital S.p.A., in its quality of Manufacturer of the In Vitro Diagnostic Medical Devices, is the exclusive responsible for this Declaration of Conformity.

The present EU Declaration of Conformity is valid up to substantial changes will be applied requiring an amendment to regulatory requirements and regards the batches produced by this date.

Route for CE mark:

According to Annex II and III of EU Regulation 2017/746.

Applicable Standards & Common Specifications:

No applicable common specifications are currently in force.

The list of harmonized standards applied is included in Annex 1 of this Declaration.

Trieste, 06.10.2025

PRRC and Technical Director



Dr. Giulia Kropf



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Code (REF)	EC Marking from	Commercial Name	Intended purpose
9190NT	2023.10.26	Eu-Fast Reader	Eu-Fast Reader is a non-automated IVD rapid test reader for the quantitative interpretation of Eurospital rapid tests such as CalFast XT, CalFast NeXT, ElaFast, IFX-Fast and ADM-Fast, aimed as an aid for identifying and monitoring different chronic inflammatory human pathologies, starting from fecal and serological biological samples. For professional use only.
9190	2024.02.19	CalFast Reader	CalFast Reader is a non-automated IVD rapid test reader for the quantitative interpretation of Eurospital rapid tests such as CalFast XT, CalFast NeXT, ElaFast, aimed as an aid for identifying and monitoring different chronic inflammatory human pathologies, starting from faecal biological samples. For professional use only.

Call



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ANNEX 1 – List of harmonized standards applied

EN ISO 13485:2016/A11:2021

EN ISO 14971:2019/A11:2021

EN ISO 15223-1:2021

A handwritten signature in black ink, appearing to be "C. K.", located below the list of standards.