DICHIARAZIONE DI CONFORMITA'

DECLARATION OF CONFORMITY

INSIDE INNOVATION

Rev. 1.1 –2021-05-13

Il Fabbricante *The Manufacture*	**ALIFAX S.r.l.**
Sede legale *Registered Office*	**via Petrarca 2/1** **35020 POLVERARA (PD)** **ITALY**
Sede produttiva *Manufacturing Site*	**via Merano 30** **33045 NIMIS (UD)** **ITALY**

Dichiara sotto la propria responsabilità che il dispositivo:
Declares on his own responsibility that the device:

Nome *Name* *(Ref.)*	URO-QUICK SCREENING KIT SI 390.900

Destinazione d'uso	***Intended use***
Kit per lo screening colturale rapido dei microrganismi responsabili delle infezioni delle vie urinarie	Kit for the rapid cultural screening of microorganisms responsible for urinary tract infections.

E' conforme ai requisiti essenziali della Direttiva 98/79/CE relativa ai Dispositivi Medico Diagnostici In Vitro (IVD)
Complies with the essential requirements of the Directive 98/79/EC related to the In Vitro Diagnostic Medical Devices (IVDD)

CE

Il prodotto è stato marcati CE come "altro dispositivo Medico Diagnostico in Vitro" secondo l'Allegato III in quanto non rientrano negli elenchi A e B dell'allegato II della Direttiva 98/79/CE
The product has been CE Marked as other IVD Medical Device according to Annex III as they are neither in List A nor in List B of Annex II of the Directive 98/79/EC

Si dichiara inoltre che i dispositivi medici sono stati progettati e fabbricati in conformità alle seguenti:
We declare also that the medical devices have been designed and manufactured in conformity to the below:

Norme armonizzate /*Harmonized standards:*

EN ISO 13485:2016/AC:2018: Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012: Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 18113-1:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011: In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

Ogni modifica ai dispositivi eseguita senza l'approvazione del Fabbricante fa decadere la presente Dichiarazione di Conformità.
Any modification to the devices without the prior consent of the Manufacturer will automatically void the present Declaration of Conformity.

Data/Issue date: 13 Maggio 2021
May 13th 2021
Località/Place: Polverara (PD) - Italy

Firma/Signature

ALIFAX s.r.l.
Managing Director
Camillo Gallano

ALIFAX S.r.l.

Registered and head office
via Petrarca, 2/1 - 35020 Polverara PD Italy
Tel. (+39) 049 0992000 **Fax** (+39) 049 5855434
info@alifax.com - info.alifax@pec.alifax.com

R&D, Design and Manufacturing Dept
via Merano, 30,33045 Nimis UD Italy
Tel. (+39) 0432 197900 **Fax** (+39) 0432 547378
info.udine@alifax.com - info.udine@pec.alifax.com