



EC DECLARATION OF CONFORMITY

according to Annex III of the Directive 98/79/EC on in vitro diagnostic medical devices.

We, **ELISABETH PHARMACON, spol. s r. o.**, as manufacturer, declare under our sole responsibility that listed in vitro diagnostic medical devices (**see attached list**) other than those covered by Annex II, self-testing medical devices and devices for performance evaluation are in conformity with Directive 98/79/EC on in vitro diagnostic medical devices.

Conformity assessment procedure include following laws, rules and standards:

- ▶ **Directive 98/79/EC** on in vitro diagnostic medical devices
- ▶ **CSN EN ISO 13485** Medical devices - Quality management system – Requirements for regulatory purposes
- ▶ **CSN EN ISO 9001** Quality management system - Requirements
- ▶ **CSN EN ISO 15223-1** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- ▶ **CSN EN 13612** Performance evaluation of in vitro diagnostic medical device
- ▶ **CSN EN ISO 23640** In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
- ▶ **CSN EN 13641** Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- ▶ **CSN EN 14971** Medical devices – Application of risk management to medical device
- ▶ **CSN EN 18113-1** In vitro diagnostic medical device - Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements.
- ▶ **CSN EN 18113-2** In vitro diagnostic medical device - Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use.
- ▶ **CSN EN 62366** Medical devices – Application of usability engineering to medical device

In Brno, Czech Republic, 10th March 2021



Quality manager



LIST OF IN VITRO MEDICAL DEVICES

Ref. No.	Name IVD	Basic UDI-DI	ID No.
90052-UNI	EliGene® Mycoplasma hom/gen UNI	85940533590052UNIXE	00043887
90049-UNI	EliGene® Ureaplasma UNI	85940533590049UNIYL	00043879
90047-UNI	EliGene® Neisseria UNI	85940533590047UNIY6	00043908
90024-UNI	EliGene® Borrelia UNI	85940533590024UNIWT	00043940
90030-UNI	EliGene® MTB UNI	85940533590030UNIWA	00043852
90058-LC	EliGene® Influenza A/B/pandemic LC	85940533590058LCSN	00043844
90061-UNI	EliGene® Anaplasma phagocytophilum UNI	85940533590061UNIXJ	00043836
90056-UNI	EliGene® Legionella pneumophila UNI	85940533590056UNIYA	00047706
90055-UNI	EliGene® Mycoplasma pneumoniae UNI	85940533590055UNIY3	00047693
90036-RT	EliGene® Adenovirus RT	85940533590036RTTJ	00039407
90054-LC	EliGene® Norovirus LC	85940533590054LCS2	00047749
90053-LC	EliGene® Enterovirus LC	85940533590053LCRV	00043860
90062-UNI	EliGene® HSV1/HSV2 UNI	85940533590062UNIXR	00047722
90040-UNI	EliGene® VZV UNI	85940533590040UNIWM	00047730
90066-NGS	EliGene® Colorectum NGS	85940533590066NGSXH	00048696
90067-NGS	EliGene® Lung NGS	85940533590067NGSXQ	00048688
90068-NGS	EliGene® GIST NGS	85940533590068NGSXX	00048661
90048-RT	EliGene® Coeliac RT	85940533590048RTU3	00039503
90048-RT28	EliGene® Coeliac RT28	85940533590048RT2857	00045540
90071-RT	EliGene® Coeliac 3.0 RT	85940533590071RTTM	00328639
90060-RT	EliGene® Spondylitis HLA-B27 RT	85940533590060RTT9	00043916
90060-C6	EliGene® Spondylitis HLA-B27 C6	85940533590060C6Q2	--
90043-50	EliGene® MTB Isolation Kit	8594053359004350NG	00039511
90051-50	EliGene® Urine Isolation Kit	8594053359005150ND	00030090
90077-RT-A	EliGene® COVID19 BASIC A RT	85940533590077RTAYS	00868889
90077-RT-A500	EliGene® COVID19 BASIC A500 RT	85940533590077RTAYS	00871762
90078-RT	EliGene® COVID19 CONFIRM RT	85940533590078RTUQ	00875667
409100	EliGene® Viral RNA/DNA FAST Isolation Kit	859405335409JN	00875675



90078-RT-500	EliGene® COVID19 CONFIRM 500 RT	85940533590078RTUQ	00920907
90079-RT	EliGene® COVID 19 Triple RIC RT	85940533590079RTUV	00920915
90079-RT-500	EliGene® COVID 19 Triple RIC 500 RT	85940533590079RTUV	00920915
90082-RT	EliGene® COVID19 UKV RT	85940533590082RTTZ	00948301
90082-RT-500	EliGene® COVID19 UKV 500 RT	85940533590082RTTZ	00948301
90083-RT	EliGene® COVID19 UKV/SAV RT	85940533590083RTU6	---
90083-RT-500	EliGene® COVID19 UKV/SAV 500 RT	85940533590083RTU6	---