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DECLARATION OF CONFORMITY

We, Fujirebio Diagnostics AB hereby declare that the products listed below comply with the In Vitro Medical Device Directive 98/79/EC and its relevant transposition into the national laws of the member states in which the devices are intended to be placed on the market.

Product name	*Prod No*	*Product grouping*
CanAg AFP EIA	600-10*	Common/Other IVD product
CanAg CA125 EIA	400-10*	Common/Other IVD product
CanAg CA15-3 EIA	200-10*	Common/Other IVD product
CanAg CA19-9 EIA	120-10*	Common/Other IVD product
CanAg CA242 EIA	101-10*	Common/Other IVD product
CanAg CEA EIA	401-10*	Common/Other IVD product
CanAg Free PSA EIA	350-10**	Annex II list B
CanAg NSE EIA	420-10*	Common/Other IVD product
CanAg ProGRP EIA	220-10*	Common/Other IVD product
CanAg PSA EIA	340-10**	Annex II list B
CanAg S100 EIA	708-10*	Common/Other IVD product
CanAg SCC EIA	800-10*	Common/Other IVD product
CanChek	107-20*	Common/Other IVD product
CYFRA 21-1 EIA	211-10*	Common/Other IVD product
HE4 EIA	404-10*	Common/Other IVD product
Tumor Marker Control	108-20**	Annex II list B
ProGRP Control	230-20*	Common/Other IVD product
Mesothelin Control	360-20*	Common/Other IVD product
Lung Marker Control	240-20*	Common/Other IVD product

* using Annex III as the conformance assessment procedure
** using Annex IV as the conformance assessment procedure.

16 February 2016, Göteborg

Fujirebio Diagnostics AB

Thomas Stjernkvist
QA & RA Manager

Digitally signed by Bolea Petru
Date: 2021.06.22 09:36:23 EEST
Reason: MoldSign Signature
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