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CERTIFICATE 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.

	Prod no	*Prod grouping*
CanAg CA242 EIA	101-10*	Common/Other IVD product
CanAg CA19-9 EIA	120-10*	Common/Other IVD product
CanAg CA15-3 EIA	200-10*	Common/Other IVD product
CanAg PSA EIA	340-10**	Annex II list B
CanAg Free PSA EIA	350-10**	Annex II list B
CanAg CA125 EIA	400-10*	Common/Other IVD product
CanAg CEA EIA	401-10*	Common/Other IVD product
CanAg NSE EIA	420-10*	Common/Other IVD product
CanAg AFP EIA	600-10*	Common/Other IVD product
CanAg S100 EIA	708-10*	Common/Other IVD product
CanAg SCC EIA	800-10*	Common/Other IVD product
CanChek Tumor Marker Control Serum	107-20*	Common/Other IVD product
HE4 EIA	404-10*	Common/Other IVD product
Cyfra 21-1 EIA	211-10*	Common/Other IVD product

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

December 1, 2009 Göteborg

Fujirebio Diagnostics AB

Christina Hall
Managing Director

Digitally signed by Bolea Petru
Date: 2021.06.22 09:35:06 EEST
Reason: MoldSign Signature
Location: Moldova