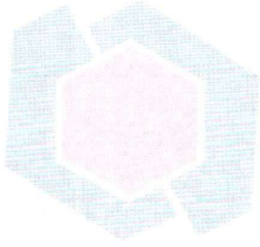


Conformity Declarations

Archem Diagnostics Systems

Declares in our own responsibility conformity of the products listed below according to the essential requirements in other IVD products the Directive 98 / 79 / EC on *in vitro* diagnostic medical devices (IVD Directive)



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ZA17B4-R1	D-Dimer Reagent
ZA17B4-R2	D-Dimer Reagent
ZA17B20-R1	D-Dimer Reagent
ZA17B20-R2	D-Dimer Reagent
PR21B1-R1	Procalcitonin Reagent
PR21B1-R2	Procalcitonin Reagent
5110M	PlasmaDiluent III
5121M	StromaLyse III
5131M	CleanAr
5120R	StromaLyse
9020R	CleanAr
5310C	PlasmaDiluent C
5321C	StromaLyse C
5330C	CleanAr
5340C	Concentrated Cleanacer
5910MN	PlasmaDiluent III
5911MN	PlasmaDiluent III
5950MN	DS Dilüent
5920MN	StromaLyse
5921MN	StromaLyse MN
5930MN	CleanAr
5931MN	CleanAr
5940MN	Concentrated Cleanacer
5941MN	PROBE CleanAr
5810AB	PlasmaDiluent
5811AB	PlasmaDiluent
5820AB	StromaLyse ABB
5821AB	StromaLyse ABB
5830AB	CleanAr
5831AB	CleanAr
5840AB	Concentrated Cleanacer
5611SW	PlasmaDiluent
5621SW	StromaLyse SW
5631SW	CleanAr
6410DN	PlasmaDiluent
6411DN	PlasmaDiluent
6420DN	StromaLyse DN
6421DN	StromaLyse DN
6430DN	CleanAr
6431DN	CleanAr
6440DN	Concentrated Cleanacer

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5410A	PlasmaDiluent A
5411A	PlasmaDiluent A
5420A	StromaLyse A
5421A	StromaLyse A
5430A	CleanAr
5431A	CleanAr
5440A	Concentrated Cleanacer
7310ER	PlasmaDiluent
7311ER	PlasmaDiluent
7320ER	StromaLyse E
7321ER	StromaLyse E
7322ER	StromaLyse E
7330ER	CleanAr
7340ER	Concentrated Cleanacer
6011MD	PlasmaDiluent III
6020MD	StromaLyse MD
6021MD	StromaLyse MD
6031MD	Cleaner MD Sample
6030MD	CleanAr
6040MD	Concentrated Cleanacer
6211HY	PlasmaDiluent
6220HY	StromaLyse HY
6221HY	StromaLyse HY
6231HY	CleanAr HY
6240HY	Concentrated Cleanacer
5211R	PlasmaDiluent
5220R	StromaLyse HY
5221R	StromaLyse HY
6510ML	PlasmaDiluent
6511ML	PlasmaDiluent
6520ML	StromaLyse DIFF
6521ML	M REF CONC
8111AR	PlasmaDiluent
8110AR	PlasmaDiluent
8112AR	PlasmaDiluent C
8120A	StromaLyse
8121A	StromaLyse
8130A	CleanAr
8131A	CleanAr
8132A	CleanAr
8140A	Concentrated Cleanacer

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6710S	PlasmaDiluent
6711S	PlasmaDiluent
6720S	StromaLyse E
6721S	StromaLyse E
6730S	CleanAr
6740S	Concentrated Cleanacer
5111M	PlasmaDiluent III
5120M	StromaLyse III
5130M	CleanAr
5125B	StromaLyse B
5128B	StromaLyse EOS
5140M	Concentrated Cleanacer
7110N	PlasmaDiluent III
7111N	PlasmaDiluent III
7210N	StromaLyse
7211N	StromaLyse
7220N	CleanAr
7230N	Concentrated Cleanacer
7010P	PlasmaDiluent
7011P	PlasmaDiluent
7020P	StromaLyse
7021P	StromaLyse
7030P	CleanAr
7031P	CleanAr
7040P	Concentrated Cleanacer
5311C	PlasmaDiluent C
5320C	StromaLyse C
5325C	StromaLyse ALFA
5231R	CleanAr
5240R	Concentrated Cleanacer
7310S	PlasmaDiluent
7320S	StromaLyse
7321S	StromaLyse
7330S	CleanAr HY
7340S	Concentrated Cleanacer
8210DW	PlasmaDiluent
8220DW	StromaLyse
8221DW	StromaLyse
8230DW	CleanAr
8240DW	Concentrated Cleanacer
8310HX	PlasmaDiluent


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Appendix to
Conformity Declarations
Archem Diagnostic Systems



Archem Sağlık San. ve Tic. A.Ş.
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Conformity also declared with all applicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:

EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director

Erkan Uca
06.10.2022


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