

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

La società KALTEK S.r.l., con sede legale e operativa in Via Liguria, 29 - 35020 Saonara (PD) Italia, accreditata in EUDAMED con il cod. SRN IT-MF-000019573

in qualità di Fabbricante, dichiara sotto la propria totale responsabilità, che i dispositivi medici di seguito indicati, destinati a essere impiegati come Dispositivi Medico-Diagnostico in vitro – Classe di rischio A - in accordo alla regola 5 dell'Allegato VIII del Regolamento UE 2017/746

- sono conformi ai requisiti generali di sicurezza e prestazione e alle disposizioni del Regolamento (UE) 2017/746 come da Fascicolo Tecnico archiviato presso la KALTEK S.r.l.;
- sono fabbricati in accordo al Fascicolo Tecnico che soddisfa i requisiti di cui all'Allegato II e III del sopra citato Regolamento;
- dichiara inoltre che, per la conformità del dispositivo, non sono state utilizzate Specifiche Comuni.

KALTEK S.r.l. with legal and operating office in Via Liguria, 29 - 35020 Saonara (PD) Italy
EUDAMED ID/SRN IT-MF-000019573

as Manufacturer, certifies on its own responsibility that the medical devices listed below, intended for use as In Vitro Diagnostic Medical Devices - Risk class A – according to rule 5 Annex VIII of the EU Regulation 2017/746

- comply with the general safety and performance requirements of the EU Regulation 2017/746 as described in the Technical File archived in KALTEK S.r.l. head office;
- are manufactured according to the Technical File which complies with the requirements of Annex II and III of the above mentioned Regulation;
- KALTEK S.r.l. also declares that no Common Specifications have been used for medical device compliance.

REAGENTI E COLORANTI

ELENCO PRODOTTI / PRODUCTS LIST

REF / COD.	DESCRIZIONE / DESCRIPTION	TAGLIO CAPACITY	BASIC UDI-DI
1003	ACIDO ACETICO 1% p/v/ ACETIC ACID 1% w/v	100 ml	805551056acido_acetico8C
1002	ACIDO ACETICO 1% p/v/ ACETIC ACID 1% w/v	500 ml	
1362	ACIDO ACETICO 2% p/p/ ACETIC ACID 2% w/w	100 ml	
1363	ACIDO ACETICO 2% p/p/ ACETIC ACID 2% w/w	500 ml	
1000	ACIDO ACETICO 3% p/p/ ACETIC ACID 3% w/w	100 ml	
1004	ACIDO ACETICO 3% p/p/ ACETIC ACID 3% w/w	500 ml	
1364	ACIDO ACETICO 4% p/p/ ACETIC ACID 4% w/w	100 ml	
1365	ACIDO ACETICO 4% p/p/ ACETIC ACID 4% w/w	500 ml	
1006	ACIDO ACETICO 5% p/p/ ACETIC ACID 5% w/w	100 ml	
1005	ACIDO ACETICO 5% p/p/ ACETIC ACID 5% w/w	500 ml	
1042	ACIDO PERIODICO per PAS 0,6% / PERIODIC ACID 0,6% w/v for P.A.S.	250 ml	805551056acido_periodEG
1082	ACIDO PERIODICO per PAS 1% / PERIODIC ACID 1% w/v for P.A.S.	1.000 ml	
1084	ACIDO PERIODICO per PAS 1% / PERIODIC ACID 1% w/v for P.A.S.	500 ml	
1044	ACIDO PICRICO SOLUZIONE 1,2% / PICRIC ACID 1,2%	500 ml	8055510561044XR
1701	ALCIAN BLUE pH 1 Dorling KIT	-	805551056alblkitph1_DorQM
1725	ALCIAN BLUE pH 2,5 SEC.DORLING KIT / ALCIAN BLUE pH 2,5 acc.DORLING KIT	-	805551056albluekit_dorIFJ
1713	ALCIAN BLUE PH 2,5 PAS KIT S. MOWRY / ALCIAN BLUE PH 2,5 PAS KIT acc. MOWRY	-	805551056albluekit_mow5D
1007	ALCIAN BLU 8GS 1% pH 2,5	250 ml	805551056alcian_blu24
1008	ALCIAN BLU 8GS 1% pH 2,5	500 ml	
1553	ALCOOL ETILICO DENAT. INCOLORE 99° / ABSOLUTE DENAT.COLORLESS ETHYL ALCOHOL	1.000 ml	805551056alcol_eti_denS5
1556	ALCOOL ETILICO DENAT. INCOLORE 99° / ABSOLUTE DENAT.COLORLESS ETHYL ALCOHOL	2.500 ml	
1554	ALCOOL ETILICO ASSOLUTO DENAT. INCOLORE/ ABSOLUTE DENAT.COLORLESS ETHYL ALCOHOL	5.000 ml	
1468	ALCOOL ETILICO DENAT. INCOLORE 96° / DENAT. 96° COLORLESS ETHYL ALCOHOL	1.000 ml	
1557	ALCOOL ETILICO DENAT. INCOLORE 96° / DENAT. 96° COLORLESS ETHYL ALCOHOL	2.500 ml	
1555	ALCOOL ETILICO DENAT. INCOLORE 96° / DENAT. 96° COLORLESS ETHYL ALCOHOL	5.000 ml	
2441	ALCOOL ETILICO DENAT. ROSA 99,9° / DENAT. 99,9° PINK ETHYL ALCOHOL	5.000 ml	
1469	ALCOOL ETILICO DENAT. ROSA 94° / DENAT. 94° PINK ETHYL ALCOHOL	5.000 ml	
1035	ALCOOL ISO 9977/3 miscela 99° / ALCOHOL ISO 9977/3 99° mixture	5.000 ml	8055510561035XQ
1646	CYTOBIOLOGIC FLUID (ROSSO) / CYTOBIOLOGIC FLUID (RED) CITOLOGY FIXATIVE	5.000 ml	8055510561646YT
1645	CYTOBIOLOGIC PAP FISSATIVO / CYTOBIOLOGIC PAP FIXATIVE	5.000 ml	8055510561645YR
1647	CYTOBIOLOGIC URINE VERDE / CYTOBIOLOGIC URINE GREEN	5.000 ml	8055510561647YV
1648	CYTOBIOLOGIC FLUIDIFICANTE / CYTOBIOLOGIC FLUIDIFIER	1.000 ml	805551056CYTOFLUS8

REF / COD.	DESCRIZIONE / DESCRIPTION	TAGLIO CAPACITY	BASIC UDI-DI
1606	CYTOTKIT 6 CON FISSATIVO KITO FLUID – WITH KITO FLUID FIXATIVE	-	805551056citokit5A
1642	CYTOTKIT 6 SLIM - CON FISSATIVO KITO FLUID – WITH KITO FLUID FIXATIVE	-	
1602	CYTOTKIT 3 CON SOLUZIONE ALCOLICA – WITH ALCOHOLIC SOLUTION	-	
2149	DECALCIFICANTE PER BIOPSIE / DECALCIFIER FOR BIOPSY WITH EDTA	1.000 ml	805551056decalcif_biopsEJ
1449	DECALCIFICANTE PER BIOPSIE / DECALCIFIER FOR BIOPSY WITH EDTA	500 ml	
4159	DECALCIFICANTE RAPIDO ACIDO / RAPID ACID DECALCIFIER	1.000 ml	8055510564159YY
2109	DECALCIFICANTE RAPIDO / RAPID DECALCIFIER	1.000 ml	8055510562109Y3
1526	DIF STAIN KIT 3 X 250 ml	3 x 250 ml	805551056dif_stainTA
1527	DIF STAIN: fissativo/fixative	500 ml	
1537	DIF STAIN: fissativo/fixative	1000 ml	
1528	DIF STAIN: colorante A/ EOSINATE STAINING SOLUTION A	500 ml	
1538	DIF STAIN: colorante A/ EOSINATE STAINING SOLUTION A	1000 ml	
1529	DIF STAIN: colorante B/ THIAZINE STAINING SOLUTION B	500 ml	
1539	DIF STAIN: colorante B/ THIAZINE STAINING SOLUTION B	1000 ml	
0605	ECOMOUNT K - MEZZO MONTANTE PER MICROSCOPIA - MOUNTING MEDIUM FOR MICROSCOPY	100 ml	805551056ecomount_kLQ
0608	ECOMOUNT K - MEZZO MONTANTE PER MICROSCOPIA - MOUNTING MEDIUM FOR MICROSCOPY	500 ml	
1114	EMALLUME DI CARAZZI / CARAZZI HEMATOXYLIN SOLUTION	250 ml	805551056emallume_carazFF
1115	EMALLUME DI CARAZZI / CARAZZI HEMATOXYLIN SOLUTION	500 ml	
1116	EMALLUME DI CARAZZI / CARAZZI HEMATOXYLIN SOLUTION	1000 ml	
1218	EMALLUME DI MAYER / MAYER HEMATOXYLIN SOLUTION	500 ml	805551056emallume_mayerKU
1100	EMALLUME DI MAYER / MAYER HEMATOXYLIN SOLUTION	1000 ml	
1518	EMALLUME DI MAYER MODIFICATO/MAYER HEMATOXYLIN MODIFIED SOLUTION	1000 ml	
1519	EMALLUME DI MAYER MODIFICATO/MAYER HEMATOXYLIN MODIFIED SOLUTION	2500 ml	
1252	EMATOSSILINA DI GILL I / GILL I HAEMATOXYLIN	1000 ml	805551056ematos_gill6M
1253	EMATOSSILINA DI GILL II / GILL II HAEMATOXYLIN	1000 ml	
1254	EMATOSSILINA DI GILL III / GILL III HAEMATOXYLIN	1000 ml	
1236	EMATOSSILINA DI HARRIS NON PAP/ HARRIS HAEMATOXYLIN NOT PAPANICOLAOU	1000 ml	8055510561236Y4
1530	EMATOSSILINA DI REGAUD/REGAUD HAEMATOXYLIN	500 ml	8055510561530Y7
1119	EOSINA SOL. ACQUOSA 1%/ EOSIN AQUEOUS SOLUTION 1%	1000 ml	805551056eosina_acquosaPK
1121	EOSINA SOL. ACQUOSA 1%/ EOSIN AQUEOUS SOLUTION 1%	500 ml	
1120	EOSINA SOL. ALCOLICA 1%/ EOSIN 1% ALCOHOLIC SOL.	2500 ml	805551056eosina_alcolicKT
1122	EOSINA SOL. ALCOLICA 0,5% / EOSIN 0,5% ALCOHOLIC SOL.	500 ml	
1123	EOSINA SOL. ALCOLICA 0,5% / EOSIN 0,5% ALCOHOLIC SOL.	1000 ml	
1501	EOSINA SOL. ALCOLICA 0,5% / EOSIN 0,5% ALCOHOLIC SOL.	2500 ml	
1533	EOSINA SOL. ALCOLICA 0,5% modificata / EOSIN 0,5% ALCOHOLIC SOL. modified	1000 ml	
1142	EOSINA- FLOXINA / EOSIN-PHLOXINE	1000 ml	8055510561142XS
1138	ESBACH REATTIVO PER ALBUMINA/ ESBACH'S REAGENT FOR ALBUMIN	1000 ml	8055510561138Y3
1608	FISSATIVO DI BOUIN / BOUIN FIXATIVE	1.000 ml	805551056fissat_bouinA3
1633	FISSATIVO DI BOUIN / BOUIN FIXATIVE	5.000 ml	
1634	FISSATIVO DI BOUIN / BOUIN FIXATIVE	10.000 ml	
1639	FISSATIVO DI DUBOSQ-BRAZIL / DUBOSQ-BRAZIL FIXATIVE	1000 ml	8055510561639YW
1657	FISSATIVO DI SACCOMANNO / SACCOMANNO FIXATIVE	1000 ml	8055510561657YY
2090	FIX-DECAL	1000 ml	8055510562090Y7
1609	FORMALDEIDE AL 4% / 4% FORMALDEHYDE	1000 ml	805551056formaldeide_4%BN
1614	FORMALDEIDE AL 4% / 4% FORMALDEHYDE	5000 ml	
1617	FORMALDEIDE AL 4% / 4% FORMALDEHYDE	10.000 ml	
1618	FORMALDEIDE AL 4% / 4% FORMALDEHYDE Kubiform	10.000 ml	
1621	FORMALDEIDE AL 4% per Tissue Filling/ 4% FORMALDEHYDE for Tissue Filling	10.000 ml	
1619	FORMALDEIDE AL 4% per Tissue Filling/ 4% FORMALDEHYDE for Tissue Filling	20.000 ml	
1616	FORMALDEIDE AL 4% / 4% FORMALDEHYDE	20.000 ml	
1636	FORMALDEIDE AL 4% / 4% FORMALDEHYDE pH 7,2-7,4	5.000 ml	
1637	FORMALDEIDE AL 4% / 4% FORMALDEHYDE pH 7,2-7,4	10.000 ml	
1638	FORMALDEIDE AL 4% / 4% FORMALDEHYDE pH 7,2-7,4	20.000 ml	
1629	FORMALINA TAMPONATA 40% / 40% BUFFERED FORMALDEHYDE	10.000 ml	805551056formtamp40%2S
1625	FORMALDEIDE AL 40% / 40% FORMALDEHYDE SOLUTION	1.000 ml	805551056formaldeid_40%49
1624	FORMALDEIDE AL 40% / 40% FORMALDEHYDE SOLUTION	2.500 ml	
1626	FORMALDEIDE AL 40% / 40% FORMALDEHYDE SOLUTION	5.000 ml	
1627	FORMALDEIDE AL 40% / 40% FORMALDEHYDE SOLUTION	10.000 ml	
1620	FORMALDEIDE AL 40% / 40% FORMALDEHYDE SOLUTION	25.000 ml	

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1610	FORMALINA B5 / B5 FORMALIN	5.000 ml	805551056formalina_B5ZD
1632	FORMALINA B5 / B5 FORMALIN	500 ml	
1635	FORMALINA ZINCATA / ZINC FORMALIN	5.000 ml	8055510561635YN
1458	FUCSINA ZIEHL-NEELSEN / ZIEHL-NEELSEN FUCHSIN	250 ml	805551056fucsina_ziehlJP
1459	FUCSINA ZIEHL-NEELSEN / ZIEHL-NEELSEN FUCHSIN	500 ml	
1460	FUCSINA ZIEHL-NEELSEN / ZIEHL-NEELSEN FUCHSIN	1.000 ml	
1158	GIEMSA	500 ml	805551056giemsaCH
1159	GIEMSA	1.000 ml	
1160	GIEMSA	2.500 ml	
1285	GRAM LUGOL	500 ml	805551056gram_lugWV
1287	GRAM DECOLORANTE / GRAM DECOLORIZER	500 ml	805551056 gram_decolorPW
1716	GROCOTT sec. CALLARD KIT	-	805551056GROCOTT_KITHV
1717	IMPREGNAZIONE ARGENTICA KIT	-	805551056impr_arg_KITXB
1276	K-CLEAR PLUS - tanica PET/PET tank	2.500 ml	805551056k-clear_plus6Y
1280	K-CLEAR PLUS - tanica PET/PET tank	5.000 ml	
1290	K-CLEAR PLUS - tanica HDPE/HDPE tank	5.000 ml	
1279	K-CLEAR	2.500 ml	805551056k-clearB7
2278	K-CLEAR	5.000 ml	
1960	KIT ATP/RVG PARAFFINA 56° / PARAFFIN 56°	4 x 2.500 ml	805551056kit_atp/rvgY3
1963	KIT ATP/RVG FORMALDEIDE AL 4% / 4% FORMALDEHYDE SOLUTION	4 x 2.500 ml	
1964	KIT ATP/RVG K-CLEAR	4 x 2.500 ml	
1965	KIT ATP/RVG XILOLO / XYLENE	4 x 2.500 ml	
1968	KIT ATP/RVG K-CLEAR PLUS	4 x 2.500 ml	
1969	KIT ATP/RVG DISIDROL 99°	4 x 2.500 ml	
1970	KIT ATP/RVG DISIDROL 96°	4 x 2.500 ml	
1971	KIT ATP/RVG ACQUA DISTILLATA / DISTILLED WATER	4 x 2.500 ml	
1974	KIT ATP/RVG ALCOOL DENAT. INCOLORE 99° / COLORLESS ETHYL ALCOHOL DENATURED 99°	4 x 2.500 ml	
1975	KIT ATP/RVG DISIDROL 70°	4 x 2.500 ml	
1976	KIT ATP/RVG ALCOOL DENAT. INCOLORE 96° / COLORLESS ETHYL ALCOHOL DENATURED 96°	4 x 2.500 ml	
1703	KIT FISSATIVO-DECALCIF.PER BOM/FIXATIVE-DECALCIF. KIT FOR BONE MARROW BIOPSIES	-	8055510561703YE
2247 - 29788	KITO FIX FISSATIVO CITOLOGICO/CYTOLOGICAL FIXATIVE	100 ml	805551056kito_fix3Y
2185 - 29789	KITO FIX FISSATIVO CITOLOGICO/CYTOLOGICAL FIXATIVE	200 ml	
1607	KITO FLUID	1.000 ml	805551056kito_fluidPD
1649	KITO FLUID	5.000 ml	
2384	KRYO SPRAY	200 ml	8055510562384YT
1224	KRYOCLEAN	250 ml	8055510561224XV
1658	LIQUIDO DI CARNOY /CARNOY FIXATIVE	500 ml	805551056liquido_carnoy3H
1604	LIQUIDO DI CARNOY /CARNOY FIXATIVE	1.000 ml	
1219	MAY-GRUNWALD	500 ml	805551056may_grunwaldFM
1220	MAY-GRUNWALD	1.000 ml	
1221	MAY-GRUNWALD	2.500 ml	
1740	MAY-GRUNWALD GIEMSA KIT x sangue / MAY-GRUNWALD GIEMSA KIT for blood	-	805551056Kit_Mgrun_GiemYB
1223	MEZZO MONTANTE ACQUOSO / ACQUEOUS MOUNTING MEDIUM	50 ml	8055510561223XT
1558	MONTANTE SINTETICO / SYNTETIC MOUNTING MEDIUM	250 ml	805551056montante_sintZL
1559	MONTANTE SINTETICO / SYNTETIC MOUNTING MEDIUM	500 ml	
0782	OCT MATRICE CRIO-IMPRIMENTE - OCT EMBEDDING MATRIX	125 ml	805551056OCTJT
1513	PAPANICOLAOU KALTEK HARRIS EMATOSSILINA/ PAPANICOLAOU KALTEK HARRIS HEMATOXYLIN	1.000 ml	805551056papanicolaou2Z
1514	PAPANICOLAOU KALTEK HARRIS EMATOSSILINA/ PAPANICOLAOU KALTEK HARRIS HEMATOXYLIN	2.500 ml	
1524	EMATOSSILINA HARRIS modificata/ HARRIS HEMATOXYLIN modified	1.000 ml	
1525	EMATOSSILINA HARRIS modificata/ HARRIS HEMATOXYLIN modified	2.500 ml	
1242	PAPANICOLAOU EA-31	500 ml	
1241	PAPANICOLAOU EA-31	1.000 ml	
1516	PAPANICOLAOU KALTEK EA-50	1.000 ml	
1517	PAPANICOLAOU KALTEK EA-50	2.500 ml	
1246	PAPANICOLAOU EA-65	500 ml	
1245	PAPANICOLAOU EA-65	1.000 ml	
1510	PAPANICOLAOU KALTEK OG6	1.000 ml	
1511	PAPANICOLAOU KALTEK OG6	2.500 ml	

REF / COD.	DESCRIZIONE / DESCRIPTION	TAGLIO CAPACITY	BASIC UDI-DI
1714	PAS KIT SEC. HOTCHKISS-MCMANUS / PAS KIT acc. HOTCHKISS-MCMANUS	-	805551056 paskit_hot_mcm 3J
1560	PER-TEK montante per vetrini / mounting medium	500 ml	8055510561560YG
1442	PICROFUCSINA VAN GIESON / VAN GIESON PICROFUCHSIN SOLUTION	1.000 ml	8055510561442Y9
0864 0763 0764 0765	PLASTIWAX PLASTIWAX PLASTIWAX PLUS PLASTIWAX X-TRA	1 Kg 2,5 Kg 2,5 Kg 2,5 Kg	805551056plastiwxC4
1264	POTASSIO PERMANGANATO 0,5%/ 0,5 POTASSIUM PERMANGANATE	500 ml	8055510561264Y9
1292	SCHIFF PER ISTOLOGIA /SCHIFF REAGENT FOR HISTOLOGY	500 ml	8055510561292YE
1333	SODIO TIOSOLFATO 5% SODIUM THIOSULPHATE 5%	1.000 ml	8055510561333Y3
1520 1521 1522 1523	SOLVET A 99° - MISCELA ALCOLICA PER ISTOLOGIA E CITOLOGIA/ ALCOHOLIC MIXTURE FOR HISTOLOGY AND CYTOLOGY SOLVET B 95° - MISCELA ALCOLICA PER ISTOLOGIA E CITOLOGIA/ ALCOHOLIC MIXTURE FOR HISTOLOGY AND CYTOLOGY SOLVET C 80° - MISCELA ALCOLICA PER ISTOLOGIA E CITOLOGIA/ ALCOHOLIC MIXTURE FOR HISTOLOGY AND CYTOLOGY SOLVET D 70° - MISCELA ALCOLICA PER ISTOLOGIA E CITOLOGIA/ ALCOHOLIC MIXTURE FOR HISTOLOGY AND CYTOLOGY	5.000 ml 5.000 ml 5.000 ml 5.000 ml	805551056solvN9
1707 1708	SUDAN III SUDAN NERO B sec. LISON	250 ml 250 ml	805551056SudanUK
1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991	TANICA ETP /TANK FOR ETP K-CLEAR TANICA ETP /TANK ETP K-CLEAR PLUS TANICA ETP /TANK ETP FORMALDEIDE AL 4%/ 4 %FORMALDEHYDE TANICA ETP /TANK ETP ACQUA DISTILLATA/DISTILLED WATER TANICA ETP /TANK ETP XILOLO / XYLENE TANICA ETP /TANK ETP ALCOOL DENAT. INC. 99° / COLORLESS DENAT. ETHYL ALCOHOL 99° TANICA ETP /TANK ETP ALCOOL DENAT. INC. 96° / COLORLESS DENAT. ETHYL ALCOHOL 96° TANICA ETP /TANK ETP DISIDROL 70° TANICA ETP /TANK ETP DISIDROL 50° TANICA ETP /TANK ETP SOLVET 100° TANICA ETP /TANK ETP SOLVET 95°	4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml 4.100 ml	805551056taniche_p_etp5B
1266	TISSUE SOFTENER	500 ml	8055510561266YD
3043 3044 3045	XILMOUNT MONTANTE PER VETRINI / MOUNTING MEDIUM FOR MICROSCOPY XILMOUNT MONTANTE PER VETRINI / MOUNTING MEDIUM FOR MICROSCOPY XILMOUNT MONTANTE PER VETRINI / MOUNTING MEDIUM FOR MICROSCOPY	100 ml 250 ml 500 ml	805551056xilmountDL
1465 1565 1575	XILOLO PER ISTOLOGIA / XYLENE FOR HISTOLOGY XILOLO PER ISTOLOGIA TANICA PET / XYLENE FOR HISTOLOGY (PET TANK) XILOLO PER ISTOLOGIA TANICA HDPE / XYLENE FOR HISTOLOGY (HDPE TANK)	2.500 ml 5.000 ml 5.000 ml	805551056xilolo_istoIV4
1735	ZIEHL-NEESEN sec. Fite 100 test / ZIEHL-NEESEN acc. Fite 100 test	-	8055510561735YT

Saonara, 16/10/2025


kaltek srl
 Il legale rappresentante
 Cortelazzo Dr. Lorenzo