

DICHIARAZIONE DI CONFORMITA' N. 01/2022
CONFORMITY DECLARATION

La Società DDKItalia S.r.l., con sede legale in Via Solari 19 – 20144 Milano, e sede operativa in Via Marche 19 – 27029 Vigevano (PV), in qualità di Fabbrikante, dichiara sotto la propria totale responsabilità, che i dispositivi medici

We undersigned DDKItalia S.r.l. with headquarter in Via Solari 19 – 20144 Milano, and operative office in Via Marche 19 – 27029 Vigevano (PV), as a manufacturer, declares under its own responsibility that medical devices

Code	UDI-DI chemicals	CND	UMDNS	GTIN-13
00-103	Acetic acid 3%	W01030799	UMDNS-17086	8033976210007
00-104	Acetic acid 5%	W01030799	UMDNS-17086	8033976210014
00-110	Hydrochloric acid Hotkiss McManus	W01030799	UMDNS-17086	8033976210021
00-115	Fosfomolibdic acid Mallory	W01030799	UMDNS-17086	8033976210038
00-116	Fosfomolibdic acid Masson	W01030799	UMDNS-17086	8033976210045
00-117	Phosphotungstic acid Heidenhain	W01030799	UMDNS-17086	8033976210052
00-120	Oxalic acid Mallory	W01030799	UMDNS-17086	8033976210069
00-136	Scott blu water 10X	W01030799	UMDNS-17086	8033976210076
00-141	Alcohol aniline Heidenhain	W01030799	UMDNS-17086	8033976210083
00-142	Alcohol borax Mowry	W01030799	UMDNS-17086	8033976210090
00-145	Formaldehyde 40%	W01030799	UMDNS-17086	8033976210106
00-160	Orange methyl indicator 0,1%	W01030799	UMDNS-17086	8033976210113
00-219	Glycerin 99,5%	W01030799	UMDNS-17086	8033976210120
Code	UDI-DI decalcifier	CND	UMDNS	GTIN-13
02-100	RDC rapid decalcifier	W01030799	UMDNS-17086	8033976210137
02-101	RDM mild decalcifier	W01030799	UMDNS-17086	8033976210144
02-102	RDO decalcifier whit EDTA slow action	W01030799	UMDNS-17086	8033976210151
02-103	RDP decalcifier whit EDTA modified Pasquini	W01030799	UMDNS-17086	8033976210168
02-104	RDF decalcifier whit fixative I	W01030705	UMDNS-17086	8033976210175
02-105	RDL decalcifier whit fixative II slow action	W01030705	UMDNS-17086	8033976210182
02-106	RDB modified rapid decalcifier (black solution)	W01030705	UMDNS-17086	8033976210199
Code	UDI-DI histology cleaner	CND	UMDNS	GTIN-13
02-122	Alcool etilico 96^ in esenzione di accise	W01030705	UMDNS-17086	8033976210205
02-123	Alcool etilico 99^ in esenzione di accise	W01030705	UMDNS-17086	8033976210212
03-101	DdClear (d-Limonene)	W01030799	UMDNS-17086	8033976210229
03-101	DdClear (d-Limonene)	W01030799	UMDNS-17086	8033976210236
03-102	Xilene	W01030799	UMDNS-17086	8033976210243
03-103	Xilene	W01030799	UMDNS-17086	8033976210250
03-107	Xilene	W01030799	UMDNS-17086	8033976210267
03-109	Greensolv isoparaffine	W01030799	UMDNS-17086	8033976210274
Code	UDI-DI mounting media	CND	UMDNS	GTIN-13
04-102-1	DdMount mounting media	W01030706	UMDNS-17086	8033976210281
04-103	DdMount low viscosity	W01030706	UMDNS-17086	8033976210298
04-102-5	DdMount low viscosity	W01030706	UMDNS-17086	8033976210304
04-105	L-Mount mounting in D-Limonene	W01030706	UMDNS-17086	8033976210311
04-107	R-Mount water base	W01030706	UMDNS-17086	8033976210328
04-108	D-Mount jelly soluble in water	W01030706	UMDNS-17086	8033976210335
04-109	Albumine glicerinate	W01030706	UMDNS-17086	8033976210342
04-110	Apathy mount	W01030706	UMDNS-17086	8033976210359

Code	UDI-DI wax	CND	UMDNS	GTIN-13
05-100	DdWax with synthetic polymer 56-58°C 5x2 Kg	W05030599	UMDNS-17086	8033976210373
05-101	ImmuWax 54-56°C (5x2 Kg)	W05030599	UMDNS-17086	8033976210380
05-102	ImmuWax II 52-54°C (5x2 Kg)	W05030599	UMDNS-17086	8033976210397
Code	UDI-DI formalin & histology fixative	CND	UMDNS	GTIN-13
07-100	Buffered formalin 4% (oxydometric)	W01030705	UMDNS-17086	8033976210403
07-101	Buffered formalin 4% (oxydometric)	W01030705	UMDNS-17086	8033976210410
07-102	Buffered formalin 4% (oxydometric)	W01030705	UMDNS-17086	8033976210427
07-103	Buffered formaline mOsm certified	W01030705	UMDNS-17086	8033976210434
Code	UDI-DI formalin & histology fixative	CND	UMDNS	GTIN-13
07-104	Buffered formalin 4% (oxydometric)	W01030705	UMDNS-17086	8033976210441
07-107-1	Millioning Carson formalin pH 7,2-7,4	W01030705	UMDNS-17086	8033976210458
07-107	Millioning Carson formalin pH 7,2-7,4	W01030705	UMDNS-17086	8033976210465
07-107-10	Millioning Carson formalin pH 7,2-7,4	W01030705	UMDNS-17086	8033976210472
07-107-20	Millioning Carson formalin pH 7,2-7,4	W01030705	UMDNS-17086	8033976210489
07-111-1	Acetate buffered formalin	W01030705	UMDNS-17086	8033976210496
07-111	Acetate buffered formalin	W01030705	UMDNS-17086	8033976210502
07-111-10	Acetate buffered formalin	W01030705	UMDNS-17086	8033976210519
07-115	DdGreen II formaline sostitute	W01030705	UMDNS-17086	8033976210526
07-116	Bouin liquid concentrate	W01030705	UMDNS-17086	8033976210533
07-116-1	Bouin solution	W01030705	UMDNS-17086	8033976210540
07-117	Bouin Hollande liquid	W01030705	UMDNS-17086	8033976210557
07-118	Bouin Hollande liquid	W01030705	UMDNS-17086	8033976210564
07-119	B5 solution	W01030705	UMDNS-17086	8033976210571
07-120	Zamboni fixative	W01030705	UMDNS-17086	8033976210588
07-121	Solution for thermostatic bath	W01030705	UMDNS-17086	8033976210595
Code	UDI-DI museum specimen fixative	CND	UMDNS	GTIN-13
16-100	Kaiserling I	W01030705	UMDNS-17086	8033976210601
16-101	Kaiserling II	W01030705	UMDNS-17086	8033976210618
Code	UDI-DI prefilled containers AFA and Safe	CND	UMDNS	GTIN-13
07-124-01-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210625
07-124-02-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210632
07-124-03-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210649
07-124-04-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210656
07-124-06-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210663
07-124-09-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210670
07-124-12-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210687
07-124-15-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210694
07-124-16-afa	Containers UE standard pre-filled normal & coloured	W05020199	UMDNS-17086	8033976210700
07-124-02-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210717
07-124-03-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210724
07-124-04-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210731
07-124-06-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210748
07-124-09-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210755
07-124-12-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210762
07-124-15-afag	AFA prefilled containers golden pack normal & colored	W05020199	UMDNS-17086	8033976210779

Code	UDI-DI prefilled containers AFA and Safe	CND	UMDNS	GTIN-13
07-124-02	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210786
07-124-03	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210793
07-124-04	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210809
07-124-06	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210816
07-124-09	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210823
07-124-12	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210830
07-124-15	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210847
07-124-16	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210854
07-130	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210861
07-131	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210878
07-133	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210885
07-143	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210892
07-144	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210908
07-145	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210915
07-147	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210922
07-148	Containers UE standard pre-filled	W05020199	UMDNS-17086	8033976210939
07-124-02-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210946
07-124-03-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210953
07-124-04S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210960
07-124-06-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210977
07-124-09-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210984
07-124-12-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976210991
07-124-15-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976211004
07-124-16-S	Containers UE standard pre-filled safe system	W05020199	UMDNS-17086	8033976211011
07-130-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211028
07-131-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211035
07-133-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211042
07-143-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211059
07-144-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211066
07-145-S	Containers transparent cap pre-filled safe system	W05020199	UMDNS-17086	8033976211073
07-147-S	Containers transparent cap pre-filled "safe system"	W05020199	UMDNS-17086	8033976211080
07-148-S	Containers transparent cap pre-filled "safe system"	W05020199	UMDNS-17086	8033976211097
07-124-02-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211103
07-124-03-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211110
07-124-04-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211127
07-124-06-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211134
07-124-09-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211141
07-124-12-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211158
07-124-15-g	Pre-filled container normal & coloured golden pack	W05020199	UMDNS-17086	8033976211165

Code	UDI-DI histology stain	CND	UMDNS	GTIN-13
09-100	Afog solution	W01030708	UMDNS-17092	8033976211172
09-101	Amman (lactofenol of Amman in solution)	W01030708	UMDNS-17092	8033976211189
09-102	Albert stain two solution	W01030708	UMDNS-17092	8033976211196
09-103	Orange G Pears	W01030708	UMDNS-17092	8033976211202
09-104	Armand (Armand staining solution)	W01030708	UMDNS-17092	8033976211219
09-105	Azocarmine G	W01030708	UMDNS-17092	8033976211226
09-106	Blue alcian pH 1,0	W01030708	UMDNS-17092	8033976211233
09-107	Blue alcian pH 2,5	W01030708	UMDNS-17092	8033976211240
09-108	Blue aniline Masson	W01030708	UMDNS-17092	8033976211257
09-109	Blue aniline (Orange G Heidenhain)	W01030708	UMDNS-17092	8033976211264
09-110	Blue aniline (Orange G Mallory)	W01030708	UMDNS-17092	8033976211271
09-111	Blue Astra pH 2,5	W01030708	UMDNS-17092	8033976211288
09-112	Bromothymol blue solution phenicated	W01030708	UMDNS-17092	8033976211295
09-113	Blue toluidine phenic solution	W01030708	UMDNS-17092	8033976211301
09-121	Blue cresyl brilliant	W0104050102	UMDNS-17092	8033976211318
09-122	Blue methylene solution polychrome	W01030708	UMDNS-17092	8033976211325
09-123	Blue methylene Mallory solution	W01030708	UMDNS-17092	8033976211332
09-124	Blue trypan water solution	W01030708	UMDNS-17092	8033976211349
09-125	Blue toluidine polychrome	W01030708	UMDNS-17092	8033976211356
09-126	Carmallume of Mayer	W01030708	UMDNS-17092	8033976211363
09-127	Carmine alum solution	W01030708	UMDNS-17092	8033976211370
09-134	Cresyl violet Kluwer Barrera	W01030708	UMDNS-17092	8033976211387
09-135	Cresyl violet according to Moore	W01030708	UMDNS-17092	8033976211394
09-136	Cresyl violet according to Gram	W0104010801	UMDNS-17092	8033976211400
09-139	Degommier auramine phenicated	W01030708	UMDNS-17092	8033976211417
09-140	Degommier decolorizer	W01030708	UMDNS-17092	8033976211424
09-141	Fast green FCF solution	W01030708	UMDNS-17092	8033976211431
09-146	Haemalum of Carazzi	W01030708	UMDNS-17092	8033976211448
09-168	Haemalum of Mayer with chloral	W01030708	UMDNS-17092	8033976211455
09-175	Haematoxylin Chloral	W01030708	UMDNS-17092	8033976211462
09-176	Haematoxylin Delafield	W01030708	UMDNS-17092	8033976211479
09-178	Haematoxylin Gill modified	W01030708	UMDNS-17092	8033976211486
09-178-2	Haematoxylin Gill II	W01030708	UMDNS-17092	8033976211493
09-180	Haematoxylin Harris modified GB	W01030708	UMDNS-17092	8033976211509
09-181	Harris haematoxylin Liscia stabilized	W01030708	UMDNS-17092	8033976211516
09-182	Harris haematoxylin AB modified	W01030708	UMDNS-17092	8033976211523
09-183	Haematoxylin Harris AB modified (acid)	W01030708	UMDNS-17092	8033976211530
09-189	Haematoxylin Heidenhain	W01030708	UMDNS-17092	8033976211547
09-202	Haematoxylin Weigert A	W01030708	UMDNS-17092	8033976211554
09-203	Haematoxylin Weigert B	W01030708	UMDNS-17092	8033976211561
09-204	Haematoxylin Phosphotunstic P.T.A.H	W01030708	UMDNS-17092	8033976211578
09-209	Eosin extra Y alcoholic solution ready to use	W01030708	UMDNS-17092	8033976211585
09-210	Eosin extra Y alcoholic stock solution	W01030708	UMDNS-17092	8033976211592
09-211	Eosin floxin alcoholic stock solution	W01030708	UMDNS-17092	8033976211608
09-212	Eosin Y solution 1%	W01030708	UMDNS-17092	8033976211615

Code	UDI-DI histology stain	CND	UMDNS	GTIN-13
09-213	Eosin Y solution 1% modified	W01030708	UMDNS-17092	8033976211622
09-214	Purified eosin alcoholic solution	W01030708	UMDNS-17092	8033976211639
09-215	Eosin extra Y alcoholic 0,5% solution	W01030708	UMDNS-17092	8033976211646
09-216	Eosin orange alcoholic solution	W01030708	UMDNS-17092	8033976211653
09-217	Eosin orange alcoholic stock solution	W01030708	UMDNS-17092	8033976211660
09-218	Erythrosine orange Dominici	W01030708	UMDNS-17092	8033976211677
09-219	Erythrosine B solution	W01030708	UMDNS-17092	8033976211684
09-220	Phenol 85%	W01030708	UMDNS-17092	8033976211691
09-221	Floxin B Gram	W0104010801	UMDNS-17092	8033976211707
09-223	Fuchsin paraldeide Gridley	W0104010801	UMDNS-17092	8033976211714
09-224	Fuchsine ponceau Masson	W0104010801	UMDNS-17092	8033976211721
09-226	Fuchsine Ziehl Neelsen solution	W0104010801	UMDNS-17092	8033976211738
09-227	Yellow methyl solution	W0104010801	UMDNS-17092	8033976211745
09-230	Geimsa R certified powder stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976211752
09-230	Geimsa R stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976211769
09-231	Giensa L stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976211776
09-232	Geimsa R stock solution dilution 1:30	W0103010399	UMDNS-17092	8033976211783
09-235	Glicoallume of Mayer	W01030708	UMDNS-17092	8033976211790
09-236	Gram basic fuchsine	W01030708	UMDNS-17092	8033976211806
09-238	Gram safranine	W01030708	UMDNS-17092	8033976211813
09-239	Gram gentian violet phenic solution	W01030708	UMDNS-17092	8033976211820
09-240	Gram-Hucker (oxalate violet crystal)	W01030708	UMDNS-17092	8033976211837
09-245	Kuhne solution (Blue methylene phenic)	W01030708	UMDNS-17092	8033976211844
09-246	Leishman solution	W01030708	UMDNS-17092	8033976211851
09-247	Luxol fast blue	W01030708	UMDNS-17092	8033976211868
09-249	Lugol (Gram's iodine)	W01030708	UMDNS-17092	8033976211875
09-250	Lugol stabilized PVP	W01030708	UMDNS-17092	8033976211882
09-251	Lugol concentrated solution	W01030708	UMDNS-17092	8033976211899
09-255	May-Grunwald (blue methylene eosin)	W0103010399	UMDNS-17092	8033976211905
09-256	May-Grunwald (blue methylene eosin)	W0103010399	UMDNS-17092	8033976211912
09-257	Mucicarmin solution	W01030708	UMDNS-17092	8033976211929
09-258	Nigrosine solution for microbiology	W01030708	UMDNS-17092	8033976211936
09-259	Nuclear fast red	W01030708	UMDNS-17092	8033976211943
09-260	New methylene blue	W01030708	UMDNS-17092	8033976211950
09-261	Orceine acetic solution	W01030708	UMDNS-17092	8033976211967
09-262	Orceine according to Shikata	W01030708	UMDNS-17092	8033976211974
09-271	Phloxine B 3% solution	W01030708	UMDNS-17092	8033976211981
09-273	Picro indigo carmine	W01030708	UMDNS-17092	8033976211998
09-274	Picrofuchsine Van Gieson	W01030708	UMDNS-17092	8033976212001
09-277	Picromallory (acid fuchsine)	W01030708	UMDNS-17092	8033976212018
09-281	Congo Red Highman solution	W01030708	UMDNS-17092	8033976212025
09-283	Red neutral solution	W01030708	UMDNS-17092	8033976212032
09-285	Red alzarine	W01030708	UMDNS-17092	8033976212049
09-287	Red Sirius Puchtler (Sirius red)	W01030708	UMDNS-17092	8033976212056
09-288	Red ponceau	W01030708	UMDNS-17092	8033976212063

Code	UDI-DI histology stain	CND	UMDNS	GTIN-13
09-292	Schiff reagent for Feulgen & Rossenbeck	W01030708	UMDNS-17092	8033976212070
09-293	Schiff reagent for Aldehyde	W01030708	UMDNS-17092	8033976212087
09-294	Schiff reagent for Histology	W01030708	UMDNS-17092	8033976212094
09-295	Shorr solution	W01030708	UMDNS-17092	8033976212100
09-297	Sudan III sutured solution	W01030708	UMDNS-17092	8033976212117
09-298	Sudan black saturated solution	W01030708	UMDNS-17092	8033976212124
09-301	Tincture of mercuriothiolate (MIF)	W01030708	UMDNS-17092	8033976212131
09-303	Turck reagent	W01030708	UMDNS-17092	8033976212148
09-306	Green malachite solution	W01030708	UMDNS-17092	8033976212155
09-308	Light green Goldner	W01030708	UMDNS-17092	8033976212162
09-309	Light green Grocott	W01030708	UMDNS-17092	8033976212179
09-310	Methyl green purified Unna	W01030708	UMDNS-17092	8033976212186
09-312	Violet crystal oxalate Gram-Hucker	W01030708	UMDNS-17092	8033976212193
09-313	Gentian violet phenic solution	W0104010801	UMDNS-17092	8033976212209
09-315	Wright's solution	W0104010802	UMDNS-17092	8033976212216
09-316	Weigert resorcin	W0104010803	UMDNS-17092	8033976212223
09-317	Saffron, Gatinai alcoholic solution	W0104010804	UMDNS-17092	8033976212230
09-318	Saffron, Gatinai alcoholic solution	W0104010805	UMDNS-17092	8033976212247
09-319	Ziehl-Neelsen microscopy solution	W0104010806	UMDNS-17092	8033976212254
09-321	Verheoff for elastic fibers	W0104010807	UMDNS-17092	8033976212261
09-322	Miller elastic stain	W0104010808	UMDNS-17092	8033976212278
09-326	Nitro blue tetrazolium	W0104010809	UMDNS-17092	8033976212285
Code	UDI-DI cytology stain	CND	UMDNS	GTIN-13
09-105	Azocarmine G	W01030708	UMDNS-17092	8033976212292
09-140	Degommier decolorizer	W01030708	UMDNS-17092	8033976212308
09-146	Haemalum of Carazzi	W01030708	UMDNS-17092	8033976212315
09-168	Haemalum of Mayer with chloral	W01030708	UMDNS-17092	8033976212322
09-175	Haematoxylin Cloradio	W01030708	UMDNS-17092	8033976212339
09-176	Haematoxylin Delafield	W01030708	UMDNS-17092	8033976212346
09-178	Haematoxylin Gill modified	W01030708	UMDNS-17092	8033976212353
09-178-2	Haematoxylin Gill II	W01030708	UMDNS-17092	8033976212360
09-181	Harris haematoxylin Liscia stabilized	W01030708	UMDNS-17092	8033976212377
09-182	Harris haematoxylin AB modified	W01030708	UMDNS-17092	8033976212384
09-189	Heidenhain haematoxylin	W01030708	UMDNS-17092	8033976212391
09-202	Weigert haematoxylin solution A	W01030708	UMDNS-17092	8033976212407
09-203	Weigert haematoxylin solution B	W01030708	UMDNS-17092	8033976212414
09-204	P.T.A.H. phosphotungstic haematoxylin	W01030708	UMDNS-17092	8033976212421
09-209	Eosin extra Y alcohol solution ready to use	W01030708	UMDNS-17092	8033976212438
09-214	Eosin purified solution	W01030708	UMDNS-17092	8033976212445
09-217	Eosin orange alcoholic solution ready to use	W01030708	UMDNS-17092	8033976212452
09-218	Erythrosine orange Dominici	W01030708	UMDNS-17092	8033976212469
09-219	Erythrosine B	W01030708	UMDNS-17092	8033976212476
09-249	Lugol (Gram's iodine)	W01030708	UMDNS-17092	8033976212483
09-250	Lugol PVP stabilized	W01030708	UMDNS-17092	8033976212490
09-251	Lugol solution for colposcopy	W01030708	UMDNS-17092	8033976212506

Code	UDI-DI cytology stain	CND	UMDNS	GTIN-13
09-258	Nigrosine solution for microbiology	W01030708	UMDNS-17092	8033976212513
09-259	Nuclear fast red	W01030708	UMDNS-17092	8033976212520
09-260	New methylen blue	W01030708	UMDNS-17092	8033976212537
09-261	Orceine acetic solution	W01030708	UMDNS-17092	8033976212544
09-263	Orange G polychromatic solution (OG6)	W01030708	UMDNS-17092	8033976212551
09-263-2	Orange G normal solution (OG6)	W01030708	UMDNS-17092	8033976212568
09-264	Orange II polychromatic solution	W01030708	UMDNS-17092	8033976212575
09-265	Polychromatic solution EA31	W01030708	UMDNS-17092	8033976212582
09-266	Polychromatic solution EA50	W01030708	UMDNS-17092	8033976212599
09-266-2	EA50 normal solution	W01030708	UMDNS-17092	8033976212605
09-267	Polychromatic solution EA65	W01030708	UMDNS-17092	8033976212612
09-270	Polychromatic haematoxylin for Cytology	W01030708	UMDNS-17092	8033976212629
09-278	Pyronin Y	W01030708	UMDNS-17092	8033976212636
09-281	Congo red solution	W01030708	UMDNS-17092	8033976212643
09-295	Shorr solution	W01030708	UMDNS-17092	8033976212650
09-297	Sudan III saturated solution	W01030708	UMDNS-17092	8033976212667
09-298	Sudan black	W01030708	UMDNS-17092	8033976212674
09-306	Malachite green	W01030708	UMDNS-17092	8033976212681
09-308	Light green Goldener	W01030708	UMDNS-17092	8033976212698
09-309	Light green Grocott	W01030708	UMDNS-17092	8033976212704
09-310	Methyl green purified Unna	W01030708	UMDNS-17092	8033976212711
09-311	Victoria blue solution for HBsAg and elastic fibers	W01030708	UMDNS-17092	8033976212728
09-315	Wright's stain	W01030708	UMDNS-17092	8033976212735
09-317	Saffron Gatinai alcoholic solution	W01030708	UMDNS-17092	8033976212742
09-324	Pararosaniline solution	W01030708	UMDNS-17092	8033976212759
09-325	Oil red O	W01030708	UMDNS-17092	8033976212766
Code	UDI-DI hematology stain	CND	UMDNS	GTIN-13
09-101	Amman (lactofenol of Amman in solution)	W01030708	UMDNS-17092	8033976212773
09-110	Blue aniline (Orange G Mallory)	W01030708	UMDNS-17092	8033976212780
09-111	Blue Astra pH 2,5	W01030708	UMDNS-17092	8033976212797
09-112	Bromothymol blue solution	W01030708	UMDNS-17092	8033976212803
09-113	Blue toluidine phenic solution	W01030708	UMDNS-17092	8033976212810
09-120	Blue lactophenol	W01030708	UMDNS-17092	8033976212827
09-121	Blue cresyl brilliant	W0104050102	UMDNS-17092	8033976212834
09-122	Blue methylene polychrome solution	W01030708	UMDNS-17092	8033976212841
09-123	Blue methylene Mallory solution	W01030708	UMDNS-17092	8033976212858
09-124	Blue trypan water solution	W01030708	UMDNS-17092	8033976212865
09-125	Blue toluidine polychrome	W01030708	UMDNS-17092	8033976212872
09-209	Eosin extra Y alcoholic solution ready to use	W01030708	UMDNS-17092	8033976212889
09-230	Geimsa R certified powder stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976212896
09-230	Geimsa R stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976212902
09-231	Giemsal stock solution dilution 1:20	W0103010399	UMDNS-17092	8033976212919
09-232	Giemsal Liscia modified stock solution dilution 1:30	W0103010399	UMDNS-17092	8033976212926
09-245	Kuhne solution (Blue methylene phenic)	W0103010399	UMDNS-17092	8033976212933
09-246	Leishman stain	W0103010399	UMDNS-17092	8033976212940

Code	UDI-DI hematology stain	CND	UMDNS	GTIN-13
09-247	Luxol fast blue	W0103010399	UMDNS-17092	8033976212957
09-249	Lugol (Gram's iodine)	W0103010399	UMDNS-17092	8033976212964
09-250	Lugol stabilized PVP	W0103010399	UMDNS-17092	8033976212971
09-251	Lugol concentrated solution	W0103010399	UMDNS-17092	8033976212988
09-253	Mayer whit fenolfaleine	W0103010399	UMDNS-17092	8033976212995
09-255	May-Grunwald (blue methylene eosin)	W0103010399	UMDNS-17092	8033976213008
09-256	May-Grunwald (blue methylene eosin)	W0103010399	UMDNS-17092	8033976213015
09-315	Wright stain	W0103010399	UMDNS-17092	8033976213022
09-323	Wright-Giemsa modified solution	W0103010399	UMDNS-17092	8033976213039
Code	UDI-DI microbiology	CND	UMDNS	GTIN-13
12-100	Mycobact-Fluo (fluorescence staining of TB bacilli)	W0104010801	UMDNS-17096	8033976213046
12-101	Gram-Hucker 'fast action'	W0104010801	UMDNS-17096	8033976213053
12-102	Myeloperoxidase (alphanaphtol pyronine)	W01030103	UMDNS-17096	8033976213060
12-103	Fast kit for fast staining of blood smear (3x100 ml)	W01030103	UMDNS-17096	8033976213077
12-103-1	Fast kit refill fixative 1000 ml or on request	W01030103	UMDNS-17096	8033976213084
12-103-2	Fast kit refill red 1000 ml or on request	W01030103	UMDNS-17096	8033976213091
12-103-3	Fast kit refill blue 1000 ml or on request	W01030103	UMDNS-17096	8033976213107
12-104	MIF color (not included)	W0104050102	UMDNS-17096	8033976213114
12-105	Sudan black	W01030103	UMDNS-17096	8033976213121
12-106	Perls (1x100 ml +10x5 ml)	W01030103	UMDNS-17096	8033976213138
12-107	Masson trichrome (aniline blue)	W01030103	UMDNS-17096	8033976213145
12-108	Masson trichrome (green light)	W01030103	UMDNS-17096	8033976213152
12-109	FluOcolor (thiazine red)	W01030103	UMDNS-17096	8033976213169
12-111	Gram Nicolle	W01030103	UMDNS-17096	8033976213176
12-113	Mico Bact cold stain of Mycobact 3x100 ml	W01030103	UMDNS-17096	8033976213183
12-114	Mico Bact cold stain of Mycobact 2x100 ml	W01030103	UMDNS-17096	8033976213190
12-115	Mieloperoxidase Kaplow method	W01030103	UMDNS-17096	8033976213206
12-116	Haematoxylin eosin rapid 3x500 ml	W01030103	UMDNS-17096	8033976213213
12-119	Colloidal gold Muller	W01030103	UMDNS-17096	8033976213220
12-120	Colloidal gold Hale	W01030103	UMDNS-17096	8033976213237
12-127	Liscia & DeMarchi rapid cytology stain (3x500 ml)	W01030103	UMDNS-17096	8033976213244
12-128	Nills per neuroni	W01030103	UMDNS-17096	8033976213251
12-129	Field (fast stain for malaria) 3x100 ml	W01030103	UMDNS-17096	8033976213268
12-130	Luna for erythrocytes and eosinophils	W01030103	UMDNS-17096	8033976213275
12-137	Periodic acid schiff (pas) modified	W01030103	UMDNS-17096	8033976213282
12-138	Sudan black B staining system modified	W01030103	UMDNS-17096	8033976213299
12-139	Gomori trichrome for osteoid osteodi	W01030103	UMDNS-17096	8033976213305
12-140	Fetal hemoglobin	W01030103	UMDNS-17096	8033976213312
12-141	Neisser & Gram for poliphosphates	W01030103	UMDNS-17096	8033976213329
12-142	C.A.B. Chromotope aniline blue	W01030103	UMDNS-17096	8033976213336
12-143	Auramina rodamina colorazione rapida Baziz	W01030103	UMDNS-17096	8033976213343
12-144	Liscia & DeMarchi modified e&m rapid polychrome stain	W01030103	UMDNS-17096	8033976213350
12-146	Histo stain golden kit (colorazione metacromatica cinque reagenti)	W01030103	UMDNS-17096	8033976213367
12-148	Golding pap (papanicolaou soluzione non alcolica)	W01030103	UMDNS-17096	8033976213374

Code	UDI-DI microbiology	CND	UMDNS	GTIN-13
12-149	Bodians methos for nerve fibers	W01030103	UMDNS-17096	8033976213381
12-150	Gallyas silver stain	W01030103	UMDNS-17096	8033976213398
12-151	Glial fibers Holzer's	W01030103	UMDNS-17096	8033976213404
12-152	Schaeffer & Fulton's spore stain	W01030103	UMDNS-17096	8033976213411
12-153	Albert stain per Corynebacterium diphtheriae	W01030103	UMDNS-17096	8033976213428
12-154	HBFP haematoxylin basic fuchsin picric acid	W01030103	UMDNS-17096	8033976213435
Code	UDI-DI histopathology	CND	UMDNS	GTIN-13
14-100	AgNOR	W01030103	UMDNS-17086	8033976213442
14-101	Alcian blu pH 0,5	W01030103	UMDNS-17086	8033976213459
14-101	Alcian blue pH 1,0	W01030103	UMDNS-17086	8033976213466
14-102	Alcian blue pH 2,5	W01030103	UMDNS-17086	8033976213473
14-103	Alcian blue PAS	W01030103	UMDNS-17086	8033976213480
14-104	Azan trichrome	W01030103	UMDNS-17086	8033976213497
14-105	Diastase digestion method	W01030103	UMDNS-17086	8033976213503
14-106	Digestion hyaluronidase method	W01030103	UMDNS-17086	8033976213510
14-107	PTAH phosphotungstic hematoxylin	W01030103	UMDNS-17086	8033976213527
14-108	Feulgen	W01030103	UMDNS-17086	8033976213534
14-109	Fouchet Van Gieson	W01030103	UMDNS-17086	8033976213541
14-110	Fuchsin paraldeide Gomori	W01030103	UMDNS-17086	8033976213558
14-111	Gram	W01030103	UMDNS-17086	8033976213565
14-112	Grimelius	W0103010102	UMDNS-17086	8033976213572
14-113	Grocott	W0103010102	UMDNS-17086	8033976213589
14-114	Silver stain Gomori	W0103010102	UMDNS-17086	8033976213596
14-115	Luxol fast blue Kluwer Barrera	W0103010102	UMDNS-17086	8033976213602
14-116	Mallory trichrome	W0103010102	UMDNS-17086	8033976213619
14-117	Masson Fontana	W0103010102	UMDNS-17086	8033976213626
14-118	Masson trichrome	W0103010102	UMDNS-17086	8033976213633
14-119	Masson trichrome Goldner	W0103010102	UMDNS-17086	8033976213640
14-120-1	Giemsa for elicobacter pylori	W0103010102	UMDNS-17086	8033976213657
14-120-2	May Grunwald Giemsa	W0103010102	UMDNS-17086	8033976213664
14-120-3	May Grunwald Giemsa for smear	W0103010102	UMDNS-17086	8033976213671
14-122	PAS Hotchkiss McManus	W0103010102	UMDNS-17086	8033976213688
14-123	PAS Morel Maronger	W0103010102	UMDNS-17086	8033976213695
14-124	Perls Van Gieson	W0103010102	UMDNS-17086	8033976213701
14-125	Picromallory	W0103010102	UMDNS-17086	8033976213718
14-126	Rhodamina modified MCF	W0103010102	UMDNS-17086	8033976213725
14-127	Congo red	W0103010102	UMDNS-17086	8033976213732
14-128	Silver methenamine P.A.S.M	W0103010102	UMDNS-17086	8033976213749
14-129	Van Gieson trichrome	W0103010102	UMDNS-17086	8033976213756
14-130	Green methyl pironine	W0103010102	UMDNS-17086	8033976213763
14-131	Von Kossa	W0103010102	UMDNS-17086	8033976213770
14-132	Warthin Starry	W0103010102	UMDNS-17086	8033976213787
14-133	Weigert's	W0103010102	UMDNS-17086	8033976213794
14-134	Weigert's fast	W0103010102	UMDNS-17086	8033976213800
14-135	Weigert's Van Gieson	W0103010102	UMDNS-17086	8033976213817

Code	UDI-DI histopathology	CND	UMDNS	GTIN-13
14-136	Weigert's Van Gieson fast	W0103010102	UMDNS-17086	8033976213824
14-137	Ziehl-Nelssen	W0103010102	UMDNS-17086	8033976213831
14-138	Ziehl-Nelssen Fite	W0103010102	UMDNS-17086	8033976213848
14-139	High iron diammine (intestinal metaplasia)	W0103010102	UMDNS-17086	8033976213855
14-140	Pas Mayer	W0103010102	UMDNS-17086	8033976213862
14-141	Sweet & Gordon	W0103010102	UMDNS-17086	8033976213879
14-142	Kinyoun modified acid fast stain	W0103010102	UMDNS-17086	8033976213886
14-143	Gridley's for Amoeba	W0103010102	UMDNS-17086	8033976213893
14-144	Kreiberg (alcian green)	W0103010102	UMDNS-17086	8033976213909
14-145	E.P.S.R. (elastic picro Sirius red)	W0103010102	UMDNS-17086	8033976213916
14-146	Oil red O for frozen section	W0103010102	UMDNS-17086	8033976213923
14-146-P	Oil red O for section	W0103010102	UMDNS-17086	8033976213930
14-147	Yellow alcian toluidine blu	W0103010102	UMDNS-17086	8033976213947
14-148	Bielschowsky	W0103010102	UMDNS-17086	8033976213954
14-150	Blue Nile for neutral lipid	W0103010102	UMDNS-17086	8033976213961
14-151	Ether and Lojda for phospolipid	W0103010102	UMDNS-17086	8033976213978
14-152	MBS for fibrin stain	W0103010102	UMDNS-17086	8033976213985
14-153	Orcein for elastic fibres	W0103010102	UMDNS-17086	8033976213992
14-154	Castaneda's for rickettsiae	W0103010102	UMDNS-17086	8033976214005
14-155	AFOG for renal biopsy	W0103010102	UMDNS-17086	8033976214012
14-156	BOM bone marrow biopsy	W0103010102	UMDNS-17086	8033976214029
14-157	Acridine orange for plasmodium and DNA	W0103010102	UMDNS-17086	8033976214036
14-158	Malachite green	W0103010102	UMDNS-17086	8033976214043
14-159	Gomori trichrome	W0103010102	UMDNS-17086	8033976214050
14-160	Verhoeff Van Gieson for elastic fibers	W0103010102	UMDNS-17086	8033976214067
14-161	Jones' Methenamine Silver Stain (JMS)	W0103010102	UMDNS-17086	8033976214074
14-162	Gram Weigert's for fibrin	W0103010102	UMDNS-17086	8033976214081
14-163	Blue Victoria for HBSAg	W0103010102	UMDNS-17086	8033976214098
14-164	Tethrazolium blue	W0103010102	UMDNS-17086	8033976214104
14-165	PASM Jones	W0103010102	UMDNS-17086	8033976214111
14-166	Thioflavin S for amyloid & senile plaques	W0103010102	UMDNS-17086	8033976214128
14-167	Safranin O for cartilage	W0103010102	UMDNS-17086	8033976214135
14-168	Jones silver methenamine	W0103010102	UMDNS-17086	8033976214142
14-169	Pas-D Glycogen digestion – diastase	W0103010102	UMDNS-17086	8033976214159
14-170	Marchi staining method for denatured myelin sheath	W0103010102	UMDNS-17086	8033976214166
14-171	Gallyas-Braak for phosphorylated tau	W0103010102	UMDNS-17086	8033976214173
Code	UDI-DI sperm morphology	CND	UMDNS	GTIN-13
13-100	Moti-sperm for sperm morphology	W01030799	UMDNS-17086	8033976214180
13-101	Eosin nigrosin for sperm motility	W01030799	UMDNS-17086	8033976214197
13-102	Eosin for sperm vitality	W01030799	UMDNS-17086	8033976214203
13-103	Liscia DeMarchi for sperm morphology	W01030799	UMDNS-17086	8033976214210
13-104	Schorr for sperm morphology	W01030799	UMDNS-17086	8033976214227
13-105	Spermoscan (fast staining for spermocytograms)	W01030799	UMDNS-17086	8033976214234
13-106	Leuco test for sperm leucocytes	W01030799	UMDNS-17086	8033976214241
13-108	Sperm dilution fluid	W01030799	UMDNS-17086	8033976214258

Code	UDI-DI special solution	CND	UMDNS	GTIN-13
15-100	Loeffler metylen blue solution	W01030103	UMDNS-17086	8033976214265
15-102	Neisser acetic blue solution	W01030103	UMDNS-17086	8033976214272
15-103	Metylen blue hydroalcoholic solution	W01030103	UMDNS-17086	8033976214289
15-104	Carnoy fixative	W01030103	UMDNS-17086	8033976214296
15-106	Dubcq Brasil solution	W01030103	UMDNS-17086	8033976214302
15-109	Bradford for protein assay	W01030103	UMDNS-17086	8033976214319
15-115	Lugol acid Gins solution	W01030103	UMDNS-17086	8033976214326
15-126	Pandy's solution	W01030103	UMDNS-17086	8033976214333
15-127	Quinacrine solution	W01030103	UMDNS-17086	8033976214340
15-128	Rakoff for ormonal cytodiagnostc	W01030103	UMDNS-17086	8033976214357
15-129	Sternheimer & Malbin for urinary sediment	W01030103	UMDNS-17086	8033976214364
15-132	Davidson fixative	W01030103	UMDNS-17086	8033976214371
15-133	Nail keratin softener	W01030103	UMDNS-17087	8033976214371
Code	UDI-DI cytology consumables & archiving	CND	UMDNS	GTIN-13
22-105	D-brush for Endocervical samples	W05039080	UMDNS-17086	8033976214388
22-112	DdFix cytological fixative	W05039080	UMDNS-17086	8033976214395
22-113	DdFix cytological fixative	W05039080	UMDNS-17086	8033976214401
22-114	Saccomanno fixative	W05039080	UMDNS-17086	8033976214418
22-118	OCT gel (optimum cutting temperature) 130 gr	W05039080	UMDNS-17086	8033976214425
22-118-B	OCT blue	W05039080	UMDNS-17086	8033976214432
22-118-R	OCT red color	W05039080	UMDNS-17086	8033976214449
22-118-V	OCT green color	W05039080	UMDNS-17086	8033976214456
22-118-G	OCT yellow color	W05039080	UMDNS-17086	8033976214463
22-123	Immersion oil	W01030704	UMDNS-17086	8033976214470
22-125	Lens cleaner objectifs clearing 30 ml	W01030704	UMDNS-17086	8033976214487
22-126	Cryochem for chemical clearing of cryostate 250 ml	W01030704	UMDNS-17086	8033976214494
22-128	Blocstore 9 container for 450 block	W01030704	UMDNS-17086	8033976214500
22-132	Ecoslide 1000 container for 1000 slides	W01030704	UMDNS-17086	8033976214517
22-135	Paraclean (paraffin repellent)	W01030704	UMDNS-17086	8033976214524
07-149	THP - ThinPrep Pap cytology fixative	W01030705	UMDNS-17086	8033976214531
Code	UDI-DI cytology histology special	CND	UMDNS	GTIN-13
22-140	Cyto-d fixative for collection and fixation of sputum specimens	W05020199	UMDNS-17086	8033976214548
22-141	Cyto-d red is a hemolytic, alcohol-based general-purpose fixative solution	W05020199	UMDNS-17086	8033976214555
22-142	Cyto-d blue for preservation of cytology cells in suspension and for cytological evaluation	W05020199	UMDNS-17086	8033976214562
22-143	Mucosolvfix	W05020199	UMDNS-17086	8033976214579
22-124-2-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214586
22-124-3-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214593
22-124-4-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214609
22-124-6-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214616
22-124-9-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214623
22-124-12-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214630

Code	UDI-DI cytology histology special	CND	UMDNS	GTIN-13
22-124-15-cyg	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214647
22-124-2-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214654
22-124-3-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214661
22-124-4-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214678
22-124-6-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214685
22-124-9-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214692
22-124-12-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214708
22-124-15-cy	Container prefilled with cyto-d golden pack colored or normal	W05020199	UMDNS-17086	8033976214715
Code	UDI-DI tissue marking dyes	CND	UMDNS	GTIN-13
26-000	Tissue marking dyes kit	W0104010899	UMDNS-17086	8033976214722
26-100	Tissue marking dyes black	W0104010899	UMDNS-17086	8033976214739
26-101	Tissue marking dyes blue	W0104010899	UMDNS-17086	8033976214746
26-102	Tissue marking dyes red	W0104010899	UMDNS-17086	8033976214753
26-103	Tissue marking dyes green	W0104010899	UMDNS-17086	8033976214760
26-104	Tissue marking dyes yellow	W0104010899	UMDNS-17086	8033976214777
26-105	Tissue marking dyes orange	W0104010899	UMDNS-17086	8033976214784
26-106	Tissue marking dyes violet	W0104010899	UMDNS-17086	8033976214791

destinati a essere impiegati come Dispositivi Medico-Diagnostici 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 sono fabbricati in accordo al Fascicolo Tecnico che soddisfa i requisiti di cui all'Allegato II e III del sopra citato Regolamento

intended to be used as in vitro Diagnostic Medical Devices - Risk Class A - in accordance with rule 5 of Annex VIII of EU Regulation 2017/746

- *They comply with the general safety and performance requirements and the provisions of Regulation (EU) 2017/746 are manufactured in accordance with the Technical File that meets the requirements set out in Annex II and III of the aforementioned Regulation*

DDKItalia s.r.l.
Gino Gaspare dr De marchi (CEO)

Gino De Marchi

Milan 01-01-2022



Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI
E DEL SERVIZIO FARMACEUTICO
UFFICIO 04 EX DGFDI - DIAGNOSTICI IN VITRO

DGDMF/04/P/I.5.l.e.2/2017/97

HAVING REGARD to 98/79/EC directive concerning the in vitro diagnostic medical devices;

HAVING REGARD to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;

HAVING REGARD to the request dated 22-05-2017 submitted by the company D.D.K. Italia S.r.l. with registered place of business in Via Solari, 19 20144 Milano, Italy, C.F. 04654311002 P.I.11955240152;

WHEREAS this company paid the fees required by Ministerial Decree (D.M.) August 07, 2012;

HAVING REGARD to the official deeds;

IT IS ATTESTED

that the company D.D.K. Italia S.r.l. with registered place of business in Via Solari, 19 20144 Milano, Italy, C.F. 04654311002 P.I.11955240152, is the manufacturer and affixed CE marking as in vitro diagnostic medical devices, according to the Directive 98/79/EC, to the following products:

AFA contenitori pre-riempiti normali e colorati	AFA prefilled containers normal & colored
AFA contenitori pre-riempiti normali e colorati golden pack	AFA pre-filled container golden pack
Afog per biopsie renali	Afog for renal biopsy
Afog soluzione	Afog solution
AgNOR	AgNOR
Albert soluzione	Albert stain
Albumina di Mayer	Mayer's albumin
Albumina glicerinata	Albumine glycerinated
Alkaline phosphatase leukocyte	Alkaline phosphatase leukocyte
Alcian blu PAS	Alcian blue PAS
Alcian blu pH 0,5	Alcian blue pH 0,5
Alcian blu pH 1,0	Alcian blue pH 1,0
Alcian blu pH 2,5	Alcian blue pH 2,5
Alcian giallo toluidina blu	Yellow alcian toluidine blue
Alcian verde Kreiberg	Kreiberg (alcian green)
Alcol acido	Acid alcohol
Alcol iodato	Ethanol iodine
Alcool etilico 96^ denaturazione speciale	Ethyl alcohol 96^ special denaturation
Alcool etilico 99^ denaturazione speciale	Ethyl alcohol absolute special denaturation
Amman lattofenolo soluzione	Amman's lactophenol solution
Ammerman soluzione	Ammerman solution
Apathy montante solubile in acqua	Apathy mount water soluble mounting media
Arancio d'acridine per plasmodi e DNA	Acridine orange for plasmodies and DNA
Arancio G Pears	Orange G Pears



Arancio II	Orange II
Armand (Armand colorante)	Armand (Armand staining solution)
Auramina O Rodamina colorazione rapida	Auramin O and Rhodamin rapid stain
Azan tricromica	Azan trichrome
Azocarminio G Heidenhain	Azocarmine G Heidenhain
B5 fissativo	B5 fixative
Bielschowsky per placche senili	Bielschowsky for senile plaques
BlocStore 9 contenitore 450 cassette	BlocStore 9 cardboard container 450 block
Blu acetico di Neisser	Neisser acetic blue
Blu alcian pH 1,0 Mowry	Alcian blue pH 1,0 Mowry
Blu alcian pH 2,5 Mowry	Alcian blue pH 2,5 Mowry
Blu anilina (arancio G Heidenhain)	Aniline blue (orange G Heidenhain)
Blu anilina (arancio G Mallory)	Aniline blue (orange G Mallory)
Blu anilina Masson	Aniline blue Masson
Blu Astra pH 2,5	Blue Astra pH 2,5
Blu bromofenolo indicatore	Blue bromophenol indicator
Blu cresile brillante	Blue cresyl brilliant
Blu di bromofenolo soluzione	Blue bromophenol solution
Blu di bromotimolo soluzione fenica	Bromothymol blue solution phenicated
Blu di lattofenolo	Blue lactophenol
Blu di metilene Loeffler	Loeffler methylene blue
Blu di metilene soluzione idroalcolico	Methylene blue hydroalcoholic solution
Blu di toluidina fenico	Blue toluidine phenicated
Blu di toluidina policromo	Blue toluidine polychrome
Blu di toluidina soluzione fenicata	Toluidine blue phenicated solution
Blu di Unna soluzione	Blue Unna solution
Blu metilene Mallory	Blue methylene Mallory
Blu metilene soluzione	Blue methylene solution
Blu Nilo per lipidi neutri	Blue Nile for neutral lipid
Blu tripiano soluzione acquosa	Blue trypan water solution
BOM biopsie osteo midollari	BOM bone marrow biopsy
Bouin fissativo	Bouin fixative
Bouin fissativo soluzione concentrata	Bouin fixative concentrated solution
Bouin Holland fissativo	Bouin Holland fixative
C.A.B. cromotopo aniline blu	C.A.B. cromotopo aniline blu
Carmallume di Mayer	Mayer carmallum
Carminio allume soluzione	Carmine allum solution
Carnoy fissativo	Carnoy fixative
Castaneda per clamidia	Castaneda's stain for Rickettsiae
Colorante di Field	Field stain
Contenitore monouso per pezzi chirurgici preriempito Formalina tamponata OsM.	Containers closure UE normative prefilled with NBF or other fixative
Contenitore monouso tappo pressione per pezzi chirurgici preriempito Formalina tamponata	Containers pressure cap prefilled with NBF or other fixative
Contenitori pre-riempiti	Pre-filled containers
Contenitori UE pre-riempiti golden pack	Containers UE standard pre-filled golden pack
Contenitori pre-riempiti con cyto-d golden pack	Container prefilled with cyto-d golden pack
Contenitori pre-riempiti con cyto-d confezione normale	Container prefilled with cyto-d normal pack
Cresilvioletto di Gram	Cresyl violet according to Gram
Cresilvioletto di Moore	Cresyl violet according to Moore
Cresilvioletto Kluwer Barrera	Cresyl violet Kluwer Barrera
Cresilvioletto metacromatico	Cresyl violet metachromatic
Cristallo violetto di Gram Hücker	Crystal violet oxalate Gram Hücker
Cryochem pulizia chimica criostato	Cryochem chemical clearing of cryostat
DdClean repellente della paraffina	DdClean liquid paraffin repellent
DdClear - D-Limonene	DdClear - D-Limonene



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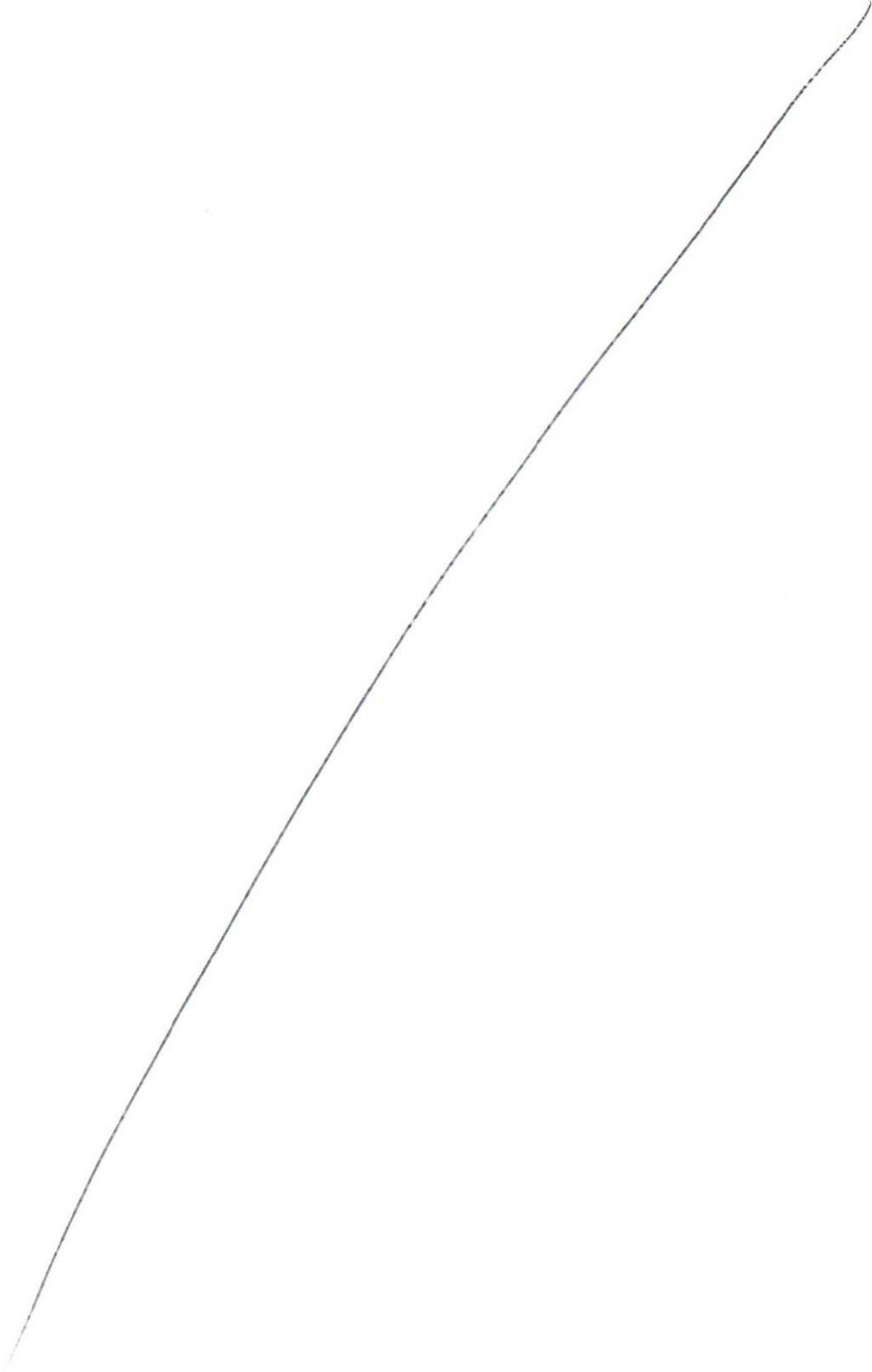
DdFix fissativo citologico	DdFix cytological fixative
DdGreen sostituto della formalina	DdGreen formalin substitute
DdMount - montante sintetico per microscopia	DdMount synthetic mounting media for electronic microscopy
DdWax paraffina con polimeri 56-58°C	DdWax with polymer added
Ddyes per bordi istologici	Ddyes tissue marking dyes
De Lounay soluzione	De Lounay solution
Degommier auramina fenicata	Degommier auramine phenicated
Degommier decolorante	Degommier decolorizer
Duboscq Brasil fissativo	Duboscq Brazil fixative
EA31 soluzione policromatica	EA31 polychromatic solution
EA50 soluzione normale	EA50 normal solution
EA50 soluzione policromatica	EA50 polychromatic solution
EA65 soluzione policromatica	EA65 polychromatic solution
EcoSlide 1000 contenitore 1000 vetrini	EcoSlide 1000 cardboard container 1000 slides
Ehder & Lojda per fosfolipidi	Ehder & Lojda for phospholipids
Emallume di Carazzi	Carazzi haemalum
Emallume di Mayer	Mayer haemalum
Ematossilina AB per sezioni in bouin	Harris haematoxylin AB for bouin sections
Ematossilina acida fosfotungstica PTAH	PTAH phosphotungstic haematoxylin
Ematossilina al Cloralio	Cloralio haematoxylin
Ematossilina di Anderson	Anderson haematoxylin
Ematossilina di Delafield	Delafield haematoxylin
Ematossilina di Ehrlich	Ehrlich haematoxylin
Ematossilina di Gill II	Gill II haematoxylin
Ematossilina di Gill modificata	Gill modified haematoxylin
Ematossilina di Harris	Harris haematoxylin
Ematossilina di Harris GB per istologia	Harris haematoxylin GB modified for histology
Ematossilina di Heidenhain (ferrica)	Heidenhain haematoxylin (ferric)
Ematossilina di Weigert A (ferrica)	Weigert A haematoxylin (ferric)
Ematossilina di Weigert B (ferrica)	Weigert B haematoxylin (ferric)
Ematossilina eosina per estemporanee	Haematoxylin eosin rapid stain
Ematossilina fosfotungstica - P.T.A.H	Haematoxylin phosphotungstic P.T.A.H
Ematossilina per Citologia	Haematoxylin for Cytology
Emoglobina fetale	Fetal hemoglobin
Eosina arancio soluzione madre alcolica	Eosin orange alcoholic stock solution
Eosina floxina soluzione madre alcolica	Eosin floxin alcoholic stock solution
Eosina nigrosina motilità dello sperma	Eosin nigrosin for sperm motility
Eosina per vitalità dello sperma	Eosin for sperm vitality
Eosina purificata in soluzione alcolica	Purified eosin alcoholic solution
Eosina Y soluzione 1% (acidificata)	Eosin Y water solution 1% (acidified)
Eosina Y soluzione acquosa 1%	Eosin Y water solution 1%
Eosina Y soluzione alcolica pronta all'uso	Eosin Y alcoholic solution ready to use
Eosina Y soluzione madre alcolica	Eosin Y alcoholic stock solution
Eritrosina arancio Dominici	Erythrosine orange Dominici
Eritrosina B soluzione	Erythrosine B solution
Fast color kit (colorazione rapida strisci)	Fast color kit (fast staining of blood smear)
Fenolo 85%	Phenol 85%
Ferocolloidale metodica Hale	Colloidal iron Hale method
Ferocolloidale metodica Muller	Colloidal iron Muller method
Feulgen	Feulgen
Field's rapido per malaria ed elicobacter	Field's stain for malaria and helicobacter
Fissativo citologico per THP	Cytology fixative for THP
Fissativo di Saccomanno	Saccomanno fixative
Fissativo di Schaudinn	Schaudinn's fixative
Floxina B soluzione	Phloxine B solution
FluOcolor (rosso tiazina)	FluOcolor (thiazine red)



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Formalina Millioning & Carson	Millioning & Carson buffered formalin
Formalina tamponata - Fissativo per Istologia	NBF neutral buffered formalin
Formalina tamponata OsM - Fissativo per Istologia (osmolarità certificata)	OsM neutral buffered formalin (osmolarity certified)
Formalina tampone acetato	NBF acetate buffer
Formalina tampone fosfato	Phosphate buffer formalin
Fosfatasi acida	Acid phosphatase
Formalina zincata	Zinc formalin
Fouchet Van Gieson	Fouchet Van Gieson
Fucsina paraldeide Gomori	Fuchsin paraldehyde Gomori
Fucsina paraldeide Gridley	Fuchsine paraldehyde Gridley
Fucsina ponceau Masson	Fuchsine ponceau Masson
Fucsina Ziehl Neelsen soluzione	Fuchsine Ziehl Neelsen solution
Giallo metanile	Yellow methyl
Giemsa L soluzione madre	Giemsa L stock solution
Giemsa R soluzione madre	Giemsa R stock solution
Giemsa R diluizione 1:30	Giemsa R stock solution dilution 1:30
Goldener tricromica per osteodi	Goldner's trichrome for osteoid
Gomori impregnazione argantica	Silver stain Gomori
Gram	Gram
Gram fucsina basica	Gram basic fuchsine
Gram Hücker (violetto ossalato Hücker)	Gram Hücker (Hücker oxalate violet crystal)
Gram Nicolle	Gram Nicolle
Gram safranina	Gram safranine
Gram violetto di genziana fenicata	Gram gentian violet phenicated solution
Gram-Hucker azione rapida	Gram-Hücker fast action
Gram-Weigert's per fibrina	Gram-Weigert's for Fibrin
Green-Par - montante in isoparaffine	Green-Par - mounting media in isoparaffin
Greensolv solvente istologico	Greensolv isoparaffin histology solvent
Gridley's per microrganismi	Gridley's for Amoeba
Grimelius	Grimelius
Grocott	Grocott
Heidenhain soluzione	Heidenhain solution
Helly soluzione	Helly solution
High iron diammine	High iron diammine
Ialuronidasi testicolare bovina	Hyaluronidase from bovine testes
ImmuWax 52-54-56°C	ImmuWax 52-54-56°C
Janus colorante tricromico	Janus trichrome stain
Kaiserling I	Kaiserling I
Kaiserling II	Kaiserling II
Kinyoun per batteri alcool-acido	Kinyoun modified acid fast stain
Kinyoun per coccidi (metodo a freddo)	Kinyoun's for coccidia (cold method)
Kinyoun soluzione	Kinyoun solution
Kolmer soluzione	Kolmer solution
Kuhne soluzione (blu di metilene fenico)	Kuhne solution (blue methylene phenicated)
Laveran (pancromica)	Laveran's (panchrome)
Leishman colorante	Leishman stain
Lens cleaner pulizia obiettivi 30 ml	Lens cleaner objectives clearing 30 ml
Leuco test per leucociti dello sperma	Leuco test for sperm leucocytes
Liscia & De Marchi (citologia rapida)	Liscia & De Marchi (fast cytology stain)
Liscia & De Marchi morfologia dello sperma	Liscia & De Marchi for sperm morphology
Liscia & De Marchi e&m colorazione rapida	Liscia & De Marchi e&m rapid polychrome stain
L-Mount - Mounting media in Limonene	L-Mount mounting media in Limonene
Lugol (iodio e ioduro di potassio)	Lugol (Gram's iodine)
Lugol acido di Gins soluzione	Lugol acid Gins solution
Lugol reattivo	Lugol's reactive
Lugol soluzione per colposcopia	Lugol solution for colposcopy





Lugol stabilizzato al PVP	Lugol PVP stabilized
Luna metodo per eritrociti ed eosinofili	Luna's method for erythrocytes and eosinophils
Luxol fast blu	Luxol fast blue
Luxol fast blu Kluwer Barrera	Luxol fast blue Kluwerl Barrera
Mallory tricromica	Mallory trichrome
Marcatore per bordi chirurgici	Tissue marking dyes kit
Masson Fontana	Masson Fontana
Masson tricromica (blu anilina)	Masson trichrome (aniline blue)
Masson tricromica (verde luce)	Masson trichrome (green light)
Masson tricromica Goldner	Masson trichrome Goldner
May Grünwald (blu di metilene eosina)	May Grünwald (blue methylene eosin)
May Grünwald Giemsa	May Grünwald Giemsa for blood smear
May Grünwald Giemsa per sezioni	May Grünwald Giemsa
Mayer alla fenoltaleina	Mayer with phenolphthalein
MBS per fibrina	MBS for fibrin stain
MGG per (elicobacter pylori)	May Grünwald Giemsa (helicobacter pylori)
Mico bact (colorazione dei micobatteri)	Myco bact (cold stain of mycobacteria)
Micobact-Fluo (fluorescenza)	Mycobact-Fluo (fluorescence)
Mieloperossidase Kaplow (benzidina)	Myeloperoxidase Kaplow method (benzidine)
Mieloperossidasi (alfanaftolo pironina)	Myeloperoxidase (alphanaphtol pyronine)
MIF (mertiolato-iodio-formalina)	MIF solution (merthiolate-iodine-formalin)
Moti-spem per morfologia dello sperma	Moti-sperm for sperm morphology
Mucicarminio soluzione	Mucicarmine solution
Naphthol AS-D chloroacetate esterase and a-naphthyl acetate esterase	Naphthol AS-D chloroacetate esterase and a-naphthyl acetate esterase
Neiseer & Gram per polifosfati	Neisser & Gram for polyphosphates
Nigrosina soluzione per microbiologia	Nigrosin solution for microbiology
Ninidrina	Ninhydrin
Nuclear fast red	Nuclear fast red
Nuovo blu di metilene	New methylene blue
OCT (vari colori) 130 gr	OCT gel (various colour) 130 gr
OCT per estemporanee 130 gr	OCT gel (optim cutting temperature) 130 gr
OG6 Arancio G soluzione	OG6 orange G solution
OG6 policromatica	OG6 polychromatic solution
Oil red O	Oil red O
Olio d'immersione 100 ml	Immersion oil for microscopy 100 ml
Orceina acetica	Orceine acetic solution
Orceina acida Shikata	Orceine according to Shikata
Orceina per fibre elastiche	Orceine for elastic fibres
P.A.S. diastasi digestione enzimatica	P.A.S. diastase digestion method
Pandy per cerebrospinali	Pandy's for cerebrospinal
PAS Hotchkiss McManus	PAS Hotchkiss McManus
Pas Mayer	Pas Mayer
PAS Morel Maronger	PAS Morel Maronger
PBS tampone	PBS buffer
Perls (1x100 ml + 10x5 ml)	Perls (1x100 ml + 10x5 ml)
Perls Van Gieson	Perls Van Gieson
Picro indigo carminio	Picro indigo carmine
Picrofucsina (Van Gieson)	Van Gieson picro fuchsine
Picromallory (arancio G)	Picromallory (orange G)
Picromallory (blu anilina)	Picromallory (blue aniline)
Picromallory (fucsina acida)	Picromallory (acid fuchsine)
Pironina Y	Pyronin Y
Quinacrina soluzione	Quinacrine solution
RDB - decalcificante rapido modificato	RDB modified rapid decalcifier
RDC - decalcificante ad azione rapida	RDC Rapid decalcifier
RDF - decalcificante con fissativo I ^A	RDF decalcifier whit fixative I



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RDL - decalcificante con fissativo II^ lento	RDL decalcifier whit fixative II slow action
RDM - decalcificante ad azione media	RDM Medium decalcifier
RDO - decalcificante per osteomidollare	RDO decalcifier whit EDTA slow action
RDP (Pasquini) - EDTA per osteomidollare	RDP decalcifier with EDTA modified Pasquini
Refill blu per fast color	Refill blue for fast color
Refill eosina per fast color	Refill eosin for fast color
Refill fissativo per fast color	Refill fixative for fast color
Rhodamina modificato secondo MCF	Rhodamine modified MCF
R-Mount - montante a base acquosa	R-Mount - water based mounting media
Rosso alizarina S	Alizarine red
Rosso Congo	Congo red
Rosso Congo Highman	Congo Red Highman
Rosso di metile soluzione	Red methyl solution
Rosso neutro soluzione	Neutral red solution
Rosso ponceau	Red ponceau
Rosso Sirio E.P.S.R.	E.P.S.R. (Sirius red)
Rosso Sirio Puchtler	Puchtler Sirius red
Rosso tiazina concentrato	Red thiazine concentrated
Sacchetti per biopsia	Biopsy bag
Safranina di Gram	Gram's safranine
Schiff Feulgen & Rossenbeck	Schiff Feulgen & Rossenbeck
Schiff reattivo per aldeidi	Schiff reagent for aldehyde
Schiff reattivo per istologia	Schiff reagent for histology
Shorr per morfologia dello sperma	Shorr for sperm morphology
Shorr soluzione	Shorr solution
Silver metenamina P.A.S.M	Silver methenamine P.A.S.M
Soluzione al Saccarosio	Sucrose solution
Soluzione collante bagno termostatico	Solution for thermostatic bath
Soluzione collante per bagno termostatico	Thermostatic bath glue
Soluzione colorante di Sargeaunt	Sargeaunt's solution
Soluzione decolorante	Destaining solution
Soluzione di Bailenger	Bailenger's stain
Soluzione di Merbromina	Merbromin solution
Soluzione di Rakoff per citodiagnostica	Rakoff solution for cytodiagnosis
Spermoscan morfologia dello sperma	Spermoscan for sperm morphology
Sternheimer e Malbin sedimenti urinari	Sternhimer and Malbin urinary sediment stain
Sudan III soluzione satura	Sudan III sutured solution
Sudan nero	Sudan black
Sudan nero B (modificato)	Sudan black B staining system (modified)
Sweet & Gordon	Sweet & Gordon
Tintura di mercuriotiolato (tecnica MIF)	Tincture of mercurothiolate (MIF technique)
Tricromica per microsporidi	Trichrome stain for microsporidia
Tricromica secondo Gomori	Gomori trichrome
Turk reattivo per conteggio leucociti	Turk's solution, for leucocyte
Van Gieson tricromica	Van Gieson trichrome
Vassoio portavetrini	Slides tray in cardboard vegetable
Verde di bromocresolo in etanolo	Green bromocresol in ethanol
Verde luce Goldner	Light green Goldner
Verde luce Grocott	Light green Grocott
Verde malachite oocisti e cryptosporidium	Malachite green (oocysts and cryptosporidium)
Verde metile pironina	Green methyl pyronin
Verde metile purificato Unna	Methyl green purified Unna
Verde solido FCF soluzione	Solid green FCF solution
Verheoff soluzione	Verheoff solution
Verhoeff Van Gieson per fibre elastiche	Verhoeff Van Gieson for elastic fibers
Violetto cristallo ossalato di Gram Hückler	Violet crystal oxalate Gram Hückler
Violetto di genziana fenicato soluzione	Gentian violet phenicated solution



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Violetto di Nicolle soluzione	Nicolle violett solution
Vittoria blu soluzione	Victoria blue solution
Von Kossa	Von Kossa
Warthin Starry	Warthin Starry
Weigert metodo lungo	Weigert's long method
Weigert metodo rapido	Weigert's fast action
Weigert resorcina	Weigert resorcine
Weigert Van Gieson metodo lungo	Weigert's Van Gieson long method
Weigert Van Gieson metodo rapido	Weigert's Van Gieson fast action
Wright colorante	Wright's stain
Xilene	Xylene
Zafferano di Gâtinais soluzione alcolica	Saffron, du Gâtinais alcoholic solution
Zamboni fissativo	Zamboni fixative
Zenker fissativo	Zenker fixative
Ziehl-Neelsen	Ziehl-Neelsen
Ziehl-Neelsen Fite	Ziehl-Neelsen Fite
Ziehl-Neelsen modificata (per coccidi)	Ziehl-Neelsen modified (for coccidia)
Ziehl-Neelsen soluzione per microscopia	Ziehl-Neelsen microscopy solution

The above mentioned products, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union.

This certificate is issued on the interested company's request according to the law and for exporting.



THE OFFICE DIRECTOR

Dr. Mauro Dionisio

Mauro Dionisio

EU CORPORATE NOTIFICATION SYSTEM



ACT-004.02-20220906-APP000033708

Actor Registration Request Assessment Performed

An actor registration assessment has been performed in EUDAMED.

The competent authority Ministero della salute - Direzione generale dei dispositivi medici e del servizio farmaceutico, Italy has verified and approved your registration request.

Following this approval, the competent authority has decided to issue a unique Single Registration Number (SRN) to your entity.

The registration request ID is APP000033708