



MEDİKAL OLUŞUM SAN. VE TİC. LTD. ŞTİ.

EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on vitro diagnostic medical devices, Annex III

Manufacturer: Medikal Oluşum San. Ve Tic. Ltd. Şti.

Address: Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi No:4 Blok: 20/2, 06980
Kahramankazan/Ankara/TURKEY

Products: Medical disinfectants, medical pathology kits and chemicals, auxiliary materials, plastic and metal medical products

Product Code	Product Description
BPOZ00002	Innoculation Loop - Yellow 1 µL
BPOZ00001	Innoculation Loop - Blue 10 µL
BPIB00003	Urine Cup 100 mL - individually packed, sterile
BPIB00005	Urine Cup 100 mL
BPVI00001	Vacuumed Urine Cup 100 mL
BPVI00007	Vacuumed Urine Cup 100 mL - individually packed, sterile
BPIB00008	Urine Cup 200 mL
BPIB00009	Urine Cup 200 mL - individually packed, sterile
BPIB00001	24 Hour Urine Container 3000 mL - white, normal capped
BPIB00002	24 Hour Urine Container 3000 mL - amber, normal capped
BPIB00008	24 Hour Urine Container 3000 mL - white, vacuumed capped
BPIB00009	24 Hour Urine Container 3000 mL - amber, vacuumed capped
BPIB00010	24 Hour Urine Container 5000 mL - white, normal capped
BPIB00011	24 Hour Urine Container 5000 mL - white, vacuumed capped
BPPS00001	Plastic Urinal
BPGK00001	Faeces Container 25 mL with spoon
BPGK00002	Faeces Container 15 mL with spoon
BPGK00005	Faeces Container 50 mL
BPTA00001	Sharps Container 0.2 Lt
BPTA00002	Sharps Container 0.5 Lt
BPTA00003	Sharps Container 0.7 Lt
BPTA00004	Sharps Container 1 Lt
BPTA00005	Sharps Container 1.3 Lt
BPTA00006	Sharps Container 2 Lt

BPTA00007	Sharps Container 3 Lt
BPTA00008	Sharps Container 5 Lt
BPTA00009	Sharps Container 7.5 Lt
BPTA00010	Sharps Container 10 Lt
BPTA00011	Sharps Container 27-30 Lt
BPTA00012	Sharps Container 30-32 Lt
BPFT00001	Falcon Tube 15 mL
BPFT00002	Falcon Tube 50 mL
BPTT00001	Test Tube 10 mL
BPEL00003	Specimen Container 1.5-2 mL
BPSP00001	Specimen Container 15 mL
BPSP00002	Specimen Container 25-30 mL
BPSP00003	Specimen Container 50 mL
BPSP00004	Specimen Container 100 mL
BPSP00005	Specimen Container 250 mL
BPSP00006	Specimen Container 500 mL
BPSP00007	Specimen Container 1000 mL
BPSP00009	Specimen Container 2000 mL
BPSP00011	Specimen Container 3000 mL
BPSP00013	Specimen Container 5000 mL
BPSP00014	Specimen Container 10 Lt
BPSP00015	Specimen Container 20 Lt
BPSK00001	Smear Slide - 2 Slides
BPSK00010	Smear Slide - 5 Slides
BPTT00001	Treatment Tray
BPPP00001	Pasteur Pipette
BPKM00001	Cardboard Mape 10 Slides
BPKM00002	Cardboard Mape 20 Slides
BPKM00003	Cardboard Mape 40 Slides
BPMT00001	Plastic Mape 20 Slides
BPKK00001	Embedding Cassette without Lid
BPKK00015	Embedding Cassette with Lid
BPKK00020	Embedding Cassette Cartridge-Lid
BMCK00001	Steel Cassette Lid
BMBM00001	Base Mould 5*5*5 mm
BMBM00002	Base Mould 10*10*5 mm
BMBM00003	Base Mould 20*20*5 mm
BMBM00004	Base Mould 20*25*7 mm
BMBM00005	Base Mould 20*30*9 mm

BMBM00006	Base Mould 25*30*5 mm
BPOC00001	Autopsy Bag
BMBA00010	Standart Block Archive Cabinet 10 Drawers 12 Division
BMBA00011	Block Archive Cabinet 10 Drawers 12 Division with Locking System
BMBA00012	Block Archive Cabinet 10 Drawers 12 Division with Wheel
BMBA00020	Standart Block Archive Cabinet 20 Drawers 12 Division
BMBA00021	Block Archive Cabinet 20 Drawers 12 Division with Locking System
BMBA00022	Block Archive Cabinet 20 Drawers 12 Division with Wheel
BMBA00015	Mega Block Archive Cabinet
BMLA00001	Standart Microscopic Slide Archive 1 Unit 12 Drawers
BMBA00002	Microscopic Slide Archive 1 Unit 12 Drawers with Spring
BMLA00010	Standart Microscopic Slide Archive 10 Unit 12 Drawers
BMLA00011	Microscopic Slide Archive 10 Unit 12 Drawers with Spring
BMLA00012	Microscopic Slide Archive 10 Unit 12 Drawers without Spring with Lock
BMLA00012	Microscopic Slide Archive 10 Unit 12 Drawers with Spring and Lock
BMLA00014	Standart Mega Microscopic Slide Archive Cabinet
BMBK00001	Staining Container - 10 Slides
BMBK00002	Staining Container - 20 Slides
BMBK00003	Staining Container - 30 Slides
BMBK00004	Staining Container - 45 Slides
BMBK00005	Staining Container - 60 Slides
BMBK00006	Staining Container - Vertical
BMLS00001	Microscopic Slide Basket - 5 Slides
BMLS00002	Microscopic Slide Basket - 10 Slides
BMLS00003	Microscopic Slide Basket - 20 Slides
BMLS00004	Microscopic Slide Basket - 30 Slides
BMLS00005	Microscopic Slide Basket - 45 Slides
BMLS00006	Microscopic Slide Basket - 60 Slides
BMPA00001	Finger Splint 10 cm
BMPA00002	Finger Splint 15 cm
BMPA00003	Finger Splint 20 cm
BMPA00004	Finger Splint 25 cm
BMPA00005	Finger Splint 30 cm
BPPK00005	Petri Dishes 90 mm without Division
BPPK00006	Petri Dishes 90 mm without Division Gamma Sterilized
BPPK00007	Petri Dishes 90 mm with Division
BPPK00008	Petri Dishes 90 mm with Division Gamma Sterilized
BPPK00001	Petri Dishes 120 mm without Division

BPPK00003	Petri Dishes 120 mm without Division Gamma Sterilized
BPPK00002	Petri Dishes 150 mm without Division
BPPK00004	Petri Dishes 150 mm without Division Gamma Sterilized
BPSN00026	Water Sampling Bottle 250 mL White
BPSN00025	Water Sampling Bottle 250 mL Amber
BPSN00024	Water Sampling Bottle 250 mL Transparent
BPSN00029	Water Sampling Bottle 500 mL White
BPSN00028	Water Sampling Bottle 500 mL Amber
BPSN00027	Water Sampling Bottle 500 mL Transparent
BPSN00033	Water Sampling Bottle 500 mL PET
BPSN00032	Water Sampling Bottle 1000 mL White
BPSN00031	Water Sampling Bottle 1000 mL Amber
BPSN00030	Water Sampling Bottle 1000 mL Transparent
BPSN00034	Water Sampling Bottle 1000 mL PET
BPSN00004	Water Sampling Bottle 250 mL White – Sodium Thiosulphate
BPSN00005	Water Sampling Bottle 250 mL Amber – Sodium Thiosulphate
BPSN00006	Water Sampling Bottle 250 mL Transparent – Sodium Thiosulphate
BPSN00010	Water Sampling Bottle 500 mL White – Sodium Thiosulphate
BPSN00011	Water Sampling Bottle 500 mL Amber – Sodium Thiosulphate
BPSN00012	Water Sampling Bottle 500 mL Transparent – Sodium Thiosulphate
BPSN00020	Water Sampling Bottle 500 mL PET – Sodium Thiosulphate
BPSN00016	Water Sampling Bottle 1000 mL White – Sodium Thiosulphate
BPSN00017	Water Sampling Bottle 1000 mL Amber – Sodium Thiosulphate
BPSN00018	Water Sampling Bottle 1000 mL Transparent – Sodium Thiosulphate
BPSN00022	Water Sampling Bottle 1000 mL PET – Sodium Thiosulphate
BPFK00001	Formalin Filled Container 8-15 mL
BPFK00019	Formalin Filled Container 8-15 mL with Safety Cap
BPFK00003	Formalin Filled Container 25-30 mL
BPFK00012	Formalin Filled Container 40 mL
BPFK00004	Formalin Filled Container 50 mL
BPFK00022	Formalin Filled Container 60 mL
BPFK00006	Formalin Filled Container 100 mL
BPFK00008	Formalin Filled Container 250 mL
BPFK00009	Formalin Filled Container 500 mL
BPFK00010	Formalin Filled Container 1000 mL
BPFK00011	Formalin Filled Container 2000 mL
BPFK00016	Formalin Filled Container 3000 mL
BPFK00017	Formalin Filled Container 5000 mL

BPFK00018	Formalin Filled Container 10 Lt
BKFO00001	Formaldehyde 10% 5 Lt
BKFO00003	Formaldehyde 10% 1 Lt
BKFO00004	Formaldehyde 37-40% 5 Lt
BKFO00002	Formaldehyde 37-40% 1 Lt
BKKS00001	Xylene 1 Lt
BKKS00002	Xylene 5 Lt
BKAS00001	Acetone 1 Lt
BKAS00005	Acetone 5 Lt
BKDS00003	Distilled Water – 500 mL
BKDS00005	Distilled Water – 1000 mL Square PET
BKDS00007	Distilled Water – 1000 mL Cylinder PET
BKDS00008	Distilled Water – 1000 mL PP Bottle
BKDS00005	Distilled Water – 5000 mL
BKBP00001	Pathology Paraffin
BKBP00002	Physiotherapy Paraffin
BKVA00001	Vaseline Liquid
BKVA00002	Vaseline Cream
BKSS00001	Smear Spray 180 mL
BKSS00002	Smear Spray 200 mL
BKAB00001	Alcian Blue PH 2.5 PAS – 100 Test
BKAB00002	Alcian Blue PH 2.5 – 100 Test
BKMT00001	Masson Tricrome – 100 Test
BKCR00001	Congo Red – 100 Test
BKDB00001	Pearl's Prussian Blue – 100 Test
BKEV00001	Elastic Van Giesson – 100 Test
BK GK00001	Giemsa Kit – 100 Test
BKGB00004	Gram Stain Kit – 100 Test
BKKV00002	Crystal Violet – 100 Test
BKMM00002	Methyl Green Pyronin – 100 Test
BKMC00001	Mucicarmine Stain – 100 Test
BKPS00001	Periodicacid Schiff – 100 Test
BKTB00001	Toluidine Blue – 100 Test
BKVG00001	Van Gieson Stain – 100 Test
BKVE00001	Verhoeff Elastic Stain – 100 Test
VKZN00001	Ziehl Neelsen – 100 Test
BKGB00001	Gram Stain Solution 250 mL * 4
BKGB00002	Gram Stain Solution 500 mL * 4
BKGB00003	Gram Stain Solution 1000 mL * 4

BKMM00001	Methylene Blue 1000 mL
BKOG00001	Orange G 500 mL
BKOG00002	Orange G 1000 mL
BKOG00003	Orange G 250 mL
BKPS00001	Periodic Acid Schiff (PAS) 500 mL
BKPS00002	Periodic Acid Schiff (PAS) 1000 mL
BKPS00003	Periodic Acid Schiff (PAS) 250 mL
BKSF00001	Fuchsin Solution 1000 mL
BKSS00001	Safranin Solution 1000 mL
BKSS00003	Schiff Solution 500 mL
BKTB00003	Toluidine Blue 1000 mL
BKTB00002	Toluidine Blue 250 mL
BKTB00001	Toluidine Blue 500 mL
BKHF00001	Holland's Fixative 1000 mL
BKGS00001	Giemsa Solution 500 mL
BKGS00002	Giemsa Solution 1000 mL
BKGS00003	Giemsa Solution 250 mL
BKGC00001	Gold Chloride 100 mL
BKHM00001	Harris Hematoxylin 500 mL
BKHM00002	Harris Hematoxylin 1000 mL
BKHM00003	Harris Hematoxylin 250 mL
BKKV00002	Cyrstal Violet 1000 mL
BKLU00001	Lugol Solution 1000 mL
BKMC00001	Mucicarmine Solution 1000 mL
BKMG00001	May Grunwald 500 mL
BKMG00002	May Grunwald 1000 mL
BKMG00003	May Grunwald 250 mL
BKMH00001	Mayers Hematoxylin 500 mL
BKMH00001	Mayers Hematoxylin 1000 mL
BKMH00001	Mayers Hematoxylin 250 mL
BKDF00001	Disinfectant 100 mL – Flip top cap
BKDF00010	Disinfectant 100 mL – Spray cap
BKDF00011	Disinfectant 250 mL – Spray cap
BKDF00003	Disinfectant 500 mL
BKDF00004	Disinfectant 1000 mL
BKDF00005	Disinfectant 5000 mL
BKDF00007	Disinfectant 20 Lt
BKDF00008	Disinfectant 30 Lt
BKEN00004	Mounting Medium 1000 mL

BKEO00002	Eosin Y 1% 1000 mL
BKEA00001	EA 50 1000 mL

Classification: Other device (all devices except Annex II and self-testing devices)

We herewith declare that the above mentioned product meets the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Medikal Oluşum San. Ve Tic. Ltd. Şti. considers following laws, rules and standards:

- **Directive 98/79/EC**

In-vitro-Diagnostic

- **EN ISO 14971**

Medical devices – Application of risk management to medical devices

- **DIN EN ISO 13485**

Quality systems – Medical devices – Particular requirements for the application of EN ISO9001

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