**Form K: MIF – MANUFACTURER’S INFORMATION FILE**

**Note: Please use this form in order to enable UNOPS from creating a short list for bidders who will be considered in the upcoming procurement for medical equipment in Yemen**

Name of Applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Applicant shall provide adequate information in response to the below questionnaire:

(This form MUST be completed for each Manufacturer that the agent represents in Yemen)

**MIF section 1: General information on the company**

| Manufacturer Name |  |
| --- | --- |
| Address |  |
| Address of manufacturing site |  |
| Website |  |

| Dealer/Agent in Yemen |  |
| --- | --- |
| Exclusive Dealership (Yes/No) | □ Yes □ No |
| Manufacturer represented since (Year) |  |

Is the agent authorized to Sell/Service the manufacturer’s products in Yemen?

□ Yes □ No

Copy of valid Authorization Certificate must be attached

**Affiliates**

If the manufacturer is owned by another company, or belongs to a group of companies, please describe structure: ……………………………..………………………..………………………..………………………..………………………..………………………..………………………..………………………..………………………..………………………..…………

**Quality Systems:**

The Manufacturer comply with the requirements of ISO 13485:2016\* □ Yes □ No

Or equivalent, please specify…………………………………………………………….

The Manufacturer comply with the requirements of ISO 9001:2015\* □ Yes □ No

Or equivalent, please specify…………………………………………………………….

The Manufacturer’s products are CE certified\* □ Yes □ No

The Manufacturer’s products are FDA certified\* □ Yes □ No

The Manufacturer’s products are TUV certified\* □ Yes □ No

\* Copies of valid certificates shall be submitted to UNOPS

**MIF section 2: Type of Medical Devices manufactured**

| Department | No | Non-Conclusive/Indicative Equipment List | Available |
| --- | --- | --- | --- |
| Imaging | 1 | MRI, CT, Angio, Fluoroscopy, X-Ray, C-Arm, Mammography, Mobile X-Ray | □ Yes □ No |
| 2 | Ultrasound (Cardiac, Eco, Gynecology, Intraoperative, Etc) | □ Yes □ No |
| 3 | Bone Densitometers | □ Yes □ No |
| 4 | Image Digitization Systems | □ Yes □ No |
| 5 | Contrast Media Injectors For Angiography/CT/MRI | □ Yes □ No |
| 6 | Aprons/Shields, Apron Racks | □ Yes □ No |
| Emergency, Critical Care & Wards | 7 | Defibrillators, AED, And External Pacemakers | □ Yes □ No |
| 8 | Electrocardiography (E.G. Multichannel ECG, Holter, Stress Test, Etc) | □ Yes □ No |
| 9 | Electromyography (EMG) & Evoked-Potential, Electroencephalography (EEG) | □ Yes □ No |
| 10 | Patient Monitoring Systems (E.G. Vital Sign Monitors, Critical Care/Theatre Patient Monitors, Central Stations, Telemetry, Capnography Etc) | □ Yes □ No |
| 11 | Ventilators/Respirators (E.G. ICU Ventilators, Transport Ventilators, CPAP, BIPAP, Nebulizers, Humidifiers Etc) | □ Yes □ No |
| 12 | Resuscitators & Ambio Bags | □ Yes □ No |
| 13 | Diagnostic Sets And Basic Parameters Monitoring (E.G. Stethoscopes, Otoscopes, Sphygmomanometers (Digital/Analogue), Thermometers, Oximeters) | □ Yes □ No |
| 14 | Laryngoscopes (E.G. Fiberoptic, Video, Etc) | □ Yes □ No |
| 15 | Procedure/Exam Lights | □ Yes □ No |
| 16 | Nurse Call Systems | □ Yes □ No |
| 17 | Flowmeters And Suction Regulators (E.G. For Oxygen, Medical Air, Vacuum, Etc) | □ Yes □ No |
| 18 | Patient Warming Units (E.G. Hypo/Hyperthermia, Forced-Air Etc) | □ Yes □ No |
| 19 | Macerators, Bedpan Washers | □ Yes □ No |
| 20 | Vein Viewer | □ Yes □ No |
| Operating Room | 21 | Anesthesia Machines | □ Yes □ No |
| 22 | Endoscopy Systems, Surgical (E.G. Rigid Scopes, Laparoscopes, Arthroscopes, Minimal Invasive Systems, Insufflators, Irrigation Pumps Etc) | □ Yes □ No |
| 23 | Suction Units (E.G. Surgical, Obstetrical, Wand Drainage Etc) | □ Yes □ No |
| 24 | Surgical Cutting & Coagulation Devices And Related Equipment (E.G. Electrosurgical Units, Argon-Enhanced Coagulation, RF Generators, Vessel Sealing, Ultrasonic Surgical Systems, Smoke Evacuation Systems, Etc) | □ Yes □ No |
| 25 | Tourniquets | □ Yes □ No |
| 26 | Power Tools (E.G. Surgical Drills, Saws, Reamers, Sternum Saw, Cast Cutters Etc) | □ Yes □ No |
| 27 | Heart-Lung Bypass Units | □ Yes □ No |
| 28 | Navigation/Image-Guided Surgery Systems | □ Yes □ No |
| 29 | Infusion Pumps (E.G. Infusion, Syringe, PCA, Feeding Etc) | □ Yes □ No |
| 30 | Surgical Lasers (E.G. CO2, Holmium, Diode, ND YAG Etc) | □ Yes □ No |
| 31 | Microscopes, Operating (E.G. Surgical, Neuro, ENT, Ophthalmology) | □ Yes □ No |
| 32 | Lithotripters (Extracorporeal And Intracorporeal) | □ Yes □ No |
| 33 | Peripheral Nerve Stimulators | □ Yes □ No |
| 34 | Operating Tables (E.G. General, Orthopedic Etc) | □ Yes □ No |
| 35 | Blood/Fluid Warmers | □ Yes □ No |
| 36 | Surgical Instruments (E.G. Scalpel, Forceps, Scissors, Retractors, Clamps Etc) | □ Yes □ No |
| 37 | Surgical Lights | □ Yes □ No |
| 38 | Headlights | □ Yes □ No |
| 39 | Ultrasonic Aspirators | □ Yes □ No |
| 40 | Scrub Sinks | □ Yes □ No |
| Diagnostic Endoscopy | 41 | Endoscopy Systems, Diagnostic (Flexible Scopes) (E.G. Endoscopes, Bronchoscopes, Colonoscopes, Sigmoidoscopies, Gastroscopes Etc) | □ Yes □ No |
| Laboratory | 42 | Analyzers And Related Equipment (E.G. Chemistry, Hematology, Immunoassay, Amino Acid, Mycobacterial, Coagulation, Glycohemoglobin, Platelet Aggregation, Urine/Refractometers, Blood Gas, PH Meter Etc) | □ Yes □ No |
| 43 | Point-Of-Care Blood Glucose Analyzers | □ Yes □ No |
| 44 | Microarray Readers | □ Yes □ No |
| 45 | Microscopes For Laboratory | □ Yes □ No |
| 46 | Microtomes (Cryostat And Rotary) | □ Yes □ No |
| 47 | Photometric Microplate Readers; Washers, Microplate | □ Yes □ No |
| 48 | Slide Stainers For Cytology/Histology | □ Yes □ No |
| 49 | Lab Spectrometers | □ Yes □ No |
| 50 | Tissue Processors | □ Yes □ No |
| 51 | Centrifuges, Shakers, Mixers | □ Yes □ No |
| 52 | Lab Incubators (Platelet, CO2 Etc) | □ Yes □ No |
| 53 | Chromatography Systems (E.G. Gas, Liquid) | □ Yes □ No |
| 54 | Balances/Scales | □ Yes □ No |
| 55 | Eye/Face Wash Sinks | □ Yes □ No |
| 56 | Biological Safety Cabinets, Fume Hoods, Grossing Stations | □ Yes □ No |
| ENT | 57 | ENT And Related Equipment (E.G. Tympanometry, Reflectometers, Otoscopes, Audiometric Booths, ENT Treatment Units Etc) | □ Yes □ No |
| Maternity And Infant Care | 58 | Infant Incubators | □ Yes □ No |
| 59 | Open-Care Units (Resuscitators), Infant Radiant Warmers | □ Yes □ No |
| 60 | Fetal Intrapartum Monitors | □ Yes □ No |
| 61 | Ultrasonic Fetal Heart Detectors | □ Yes □ No |
| 62 | Bottles Sterilizers | □ Yes □ No |
| 63 | Electric Breast Pump | □ Yes □ No |
| 64 | Neonatal Ventilators, Bubble CPAP, Nasal CPAP, Etc | □ Yes □ No |
| 65 | Phototherapy Units | □ Yes □ No |
| Medical/Hospital Furniture | 66 | Electric Patient Beds, Critical Care Beds, Birthing Beds, Pediatric Beds/Cribs | □ Yes □ No |
| 67 | Stretchers | □ Yes □ No |
| 68 | Examination Tables/Chairs | □ Yes □ No |
| 69 | Bed Side Cabinets, Overbed Tables | □ Yes □ No |
| 70 | Carts (Medication Carts, Crash/Emergency Carts, Anesthesia Carts, Etc) | □ Yes □ No |
| 71 | Work Tables/Desks, Instrument Table, Mayo Table, Dressing Table | □ Yes □ No |
| 72 | Wheelchairs | □ Yes □ No |
| 73 | Work Benches, Shelves, Storage Cabinets | □ Yes □ No |
| 74 | Stools, Chairs, Recliners | □ Yes □ No |
| 75 | IV Poles, Kick Buckets, Bowels, Hamper | □ Yes □ No |
| 76 | Phlebotomy/Blood Donation Chairs | □ Yes □ No |
| 77 | Specialized Cabinets (E.G. Fluid/Blanket Warming Cabinets, Scopes Cabinets, Scopes Drying Cabinets, Catheter Cabinet Etc) | □ Yes □ No |
| 78 | Scales (E.G. For Adults/Pediatric, Infant ) | □ Yes □ No |
| 79 | Patient Lifts, Boards, Slides Etc | □ Yes □ No |
| 80 | Refrigerators And Freezers (E.G. For Laboratory, Pharmacy, Blood Bank, Domestic Etc) | □ Yes □ No |
| 81 | Lab Furniture/Benches | □ Yes □ No |
| 82 | Curtain Rails, Curtains Fabric, Privacy Screens | □ Yes □ No |
| Ophthalmology | 83 | Tonometer, Retinoscopes, Cataract Extraction/Phacoemulsification, Corneal Topography Systems, Slit Lamp, Lens Meter, Retinoscopes, Vitrectomy/Phaco Unit Etc) | □ Yes □ No |
| Rehabilitation | 84 | Rehabilitation (E.G. Electrotherapy Units, Bicycles, Ultrasound Physical Therapy Systems, Traction Units, Cold Therapy Units, Shockwave Units, Parallel Bars, | □ Yes □ No |
| Service Columns And Headwalls/Bedhead Units | 85 | Service Columns/Pendants/Booms | □ Yes □ No |
| 86 | Headwalls/Bedhead Units And Wall Consoles | □ Yes □ No |
| Sterilization | 87 | Washer/Disinfectors | □ Yes □ No |
| 88 | Steam Sterilizers | □ Yes □ No |
| 89 | Ultrasonic Cleaners | □ Yes □ No |
| 90 | Low-Temp Sterilizers, Ethylene Oxide | □ Yes □ No |
| 91 | Autoclaves | □ Yes □ No |
| 92 | Endoscopes Disinfecting/Reprocessing | □ Yes □ No |
| 93 | Water/Air Guns | □ Yes □ No |
| 94 | Sealers, Containers/Cases, | □ Yes □ No |
| Hemodialysis | 95 | Hemodialysis Units And Apheresis Units | □ Yes □ No |
| Pulmonary | 96 | Pulmonary Function Tests | □ Yes □ No |
| 97 | Spirometers | □ Yes □ No |
| Dental | 98 | Dental Units/Chairs | □ Yes □ No |
| 99 | Dental X-Ray (Intra-Oral And Panoramic) | □ Yes □ No |
| Mortuary | 100 | Mortuary Equipment (E.G. Refrigerators, Table, Stretchers Etc) | □ Yes □ No |
| Others(Please Specify)  ………………………….. |  | Other Equipment not mentioned above (Please Specify)  ……..…..…..…..…..…..…..…..…..…..…..…..…..…..…..…..…..….. |  |

**Manufacturing license**  
Is the manufacturing site licensed by the regulatory authority?

□ Yes □ No

**Good Manufacturing Practice (GMP)**

Is the manufacturing site regularly inspected against Good Manufacturing Practice guidelines?

□ Yes □ No

If yes, please specify the identity of the inspecting authority, the date of the last inspection

**References**

Reference list for the products installed in Yemen shall be submitted to UNOPS, the list shall at least indicate:

* Name of hospital
* Product name
* Manufacturer
* Model
* Quantity installed
* Year installed

*Attachments required;* valid copy of the manufacturing license should be attached.