

## European Declaration of Conformity

Attachment to DEC0041  
5-Jun-24

<u>Catalog Number</u>	<u>Description</u>
MAK-NV-001	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Trocar Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-002	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Trocar Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-003	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Trocar Stylet...ETO.
MAK-NV-004	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Trocar Stylet...ETO.
MAK-NV-005	MAK-NV™.....21G.15 cm (6").Trocar Stylet...ETO.
MAK-NV-006	MAK-NV™.6F.20 cm (8")....21G.15 cm (6").Trocar Stylet...ETO.
MAK-NV-007	MAK-NV™.6F.20 cm (8").....ETO.
MAK-NV-008	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Trocar Stylet.0.038" (0.97 mm).80 cm (31.5").3 mm J / Straight.ETO.
MAK-NV-009	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Trocar Stylet.0.038" (0.97 mm).80 cm (31.5").3 mm J / Straight.ETO.
MAK-NV-010	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Chiba Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-011	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Chiba Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-012	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Chiba Stylet...ETO.
MAK-NV-013	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Chiba Stylet...ETO.
MAK-NV-014	MAK-NV™.....21G.15 cm (6").Chiba Stylet...ETO.
MAK-NV-015	MAK-NV™.6F.20 cm (8")....21G.15 cm (6").Chiba Stylet...ETO.
MAK-NV-016	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.15 cm (6").Chiba Stylet.0.038" (0.97 mm).80 cm (31.5").3 mm J / Straight.ETO.
MAK-NV-017	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.15 cm (6").Chiba Stylet.0.038" (0.97 mm).80 cm (31.5").3 mm J / Straight.ETO.
MAK-NV-018	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Stainless Steel.21G.20 cm (8").Trocar Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-019	MAK-NV™.6F.20 cm (8").0.018" (0.46 mm).60 cm (23.6").Nitinol.21G.20 cm (8").Trocar Stylet.0.038" (0.97 mm).150 cm (59").3 mm J / Straight.ETO.
MAK-NV-020	MAK-NV™.....21G.20 cm (8").Trocar Stylet...ETO.
MAK-NV-021	MAK-NV™.....21G.20 cm (8").Chiba Stylet...ETO.
MAK001	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).40 cm (15.7").Stainless Steel Coil Tip. Stainless Steel Core.....
MAK001N	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.....
MAK001N-60	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).60 cm (23.6").Platinum Coil Tip.Nitinol Core.....
MAK001N-80	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).80 cm (31.5").Platinum Coil Tip.Nitinol Core.....
MAK005	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Stainless Steel Core.....
MAK005-60	Merit MAK™.Merit MAK™ Guide Wire....0.018" (0.46 mm).60 cm (23.6").Platinum Coil Tip.Stainless Steel Core.....
MAK401	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Standard Needle...
MAK401-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK401-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK401N	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Standard Needle...
MAK401N-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK401N-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK401NBT	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Standard Needle.BowTie™ Guidewire insertion device..

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MAK401NEBT	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle.BowTie™ Guidewire insertion device..
MAK405	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Standard Needle...
MAK405-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK405-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK4F-10	Merit MAK™.Coaxial Introducer/DilatorPair..4F.10 cm (4").....
MAK501	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Standard Needle...
MAK501-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK501-EBNS	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK501-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Stainless Steel Coil Tip.Stainless Steel Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK501N	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Standard Needle...
MAK501N-15	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.15 cm (6").0.018" (0.46 mm).60 cm (23.6"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Standard Needle...
MAK501N-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK501N-EP	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK501N-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK501NBT	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Standard Needle.BowTie™ Guidewire insertion device..
MAK501NEBT	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle.BowTie™ Guidewire insertion device..
MAK505	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Standard Needle...
MAK505-E	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
MAK505-PED	Merit MAK™.Coaxial Mini Access Kit.Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7"). Platinum Coil Tip.Stainless Steel Core.21G.4 cm (1.6").Echo Enhanced Needle...
MAK5F-10	Merit MAK™.Coaxial Introducer/DilatorPair..5F.10 cm (4").....
MAK5F-15	Merit MAK™.Coaxial Introducer/DilatorPair..5F.15 cm (6").....
PAKM4NPD4	Merit PAK™.Pedal Access Kit..4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKM4NPD7	Merit PAK™.Pedal Access Kit..4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKM5NPD4	Merit PAK™.Pedal Access Kit..5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKM5NPD7	Merit PAK™.Pedal Access Kit..5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKS4NPD4	Merit PAK™.Stiffened Pedal Access Kit..4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKS4NPD7	Merit PAK™.Stiffened Pedal Access Kit..4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKS5NPD4	Merit PAK™.Stiffened Pedal Access Kit..5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.4 cm (1.6").Echo Enhanced Needle..Hemostasis Valve Adapter.
PAKS5NPD7	Merit PAK™.Stiffened Pedal Access Kit..5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle..Hemostasis Valve Adapter.
S-MAK401	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK401N	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK401NBT	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle.BowTie™ Guidewire insertion device..

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S-MAK401NPD	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Palladium Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK405	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK430N	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.30 cm (12").0.018" (0.46 mm).80 cm (31.5").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK430NPD	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.4F.30 cm (12").0.018" (0.46 mm).80 cm (31.5").Palladium Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK4F-10	Merit S-MAK™.Coaxial Introducer/.Stiffened Dilator Pair.4F.10 cm (4").....
S-MAK501	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Stainless Steel Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK501N	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK501N-15	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.15 cm (6").0.018" (0.46 mm).60 cm (23.6").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK501N15BT	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.15 cm (6").0.018" (0.46 mm).60 cm (23.6").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle.BowTie™ Guidewire insertion device..
S-MAK501NBT	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Nitinol Core.21G.7 cm (2.8").Echo Enhanced Needle.BowTie™ Guidewire insertion device..
S-MAK505	Merit S-MAK™.Coaxial Mini Access Kit.Stiffened Mini Access Kit.5F.10 cm (4").0.018" (0.46 mm).40 cm (15.7").Platinum Coil Tip.Stainless Steel Core.21G.7 cm (2.8").Echo Enhanced Needle...
S-MAK5F-10	Merit S-MAK™.Coaxial Introducer/.Stiffened Dilator Pair.5F.10 cm (4").....
S-MAK5F-15	Merit S-MAK™.Coaxial Introducer/.Stiffened Dilator Pair.5F.15 cm (6").....
VA-40	Valve.Valve Adapter.4F or Smaller.(1.35 mm).8" (20 cm).

"End of List"