# DECLARATION OF CONFORMITY (DoC)

*We*

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|---|---|
| Name + address + Single Registration Number of manufacturer: | **Microtek Medical LLC**<br>Three Lakes Drive<br>Northfield, IL 60093<br>U.S.A.<br>**SRN:** US-MF-000019222 |

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|---|---|
| Name + address + Single Registration Number of Authorised EU Representative: | **Microtek Medical BV**<br>Hekkehorst 24<br>7207 BN Zutphen<br>The Netherlands<br>**SRN:** NL-AR-000006076 |

*declare that the DoC is issued under our sole responsibility and belongs to the following product(s):*

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| Trade Name/Device Description | **Patient Drapes** |
| Intended Purpose/Intended Use | Patient drapes consist of synthetic materials, as well as natural materials (specific to some product types) and are intended to be used as a protective patient covering during surgical procedures. The primary purpose of the drape is to isolate a site of surgical incision from microbial or other contamination. This is a single use device. [Not to be reprocessed.] |
| Catalogue number(s) and Basic UDI-DI | See attached list |
| Class<br>per Rule(s) | I<br>Rule 1 of Annex VIII of MDR |

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| Common Specifications | None applicable |
| Other applicable Union legislation requiring an EU DoC | None applicable |
| Conformity assessment procedure | Regulation (EU) 2017/745 Annex II and III for Technical Documentation (self-assessment) |
| EN ISO 13485:2016 | Certificate No. 44 221 117845 valid until 14 August 2027 |
| Place / Date :<br>St. Paul, MN USA<br>23 OCT 2025 | Name and Function:<br><br>Lam Duong<br>*Person Responsible for Regulatory Compliance* |

MEDLINE MICROTEK

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## Listing of Devices

| Part Number | Trade Name / Part Description | Basic UDI-DI |
|---|---|---|
| 1-0815N | LINGEMAN PERCUTANEOUS PROCEDURE DRAPE | 0748426MI01PD29INZ02H |
| 3150N | FLUID COLLECTION POUCH, 10" X 11" | 0748426MI01PD30INZ0XQ |
| 3781N | SHOULDER ARTHROSCOPY FLUID COLLECTION POUCH, 32" X 30" | 0748426MI01PD29INZ02H |
| 3854N | FLUID COLLECTION POUCH, 20" X 20" | 0748426MI01PD30INZ0XQ |
| 4107N | EPIDURAL DRAPE, 40" X 32" WITH 3" FENESTRATION | 0748426MI01PD29INZ02H |
| 4638N | FLUID COLLECTION POUCH, 20" X 24" | 0748426MI01PD30INZ0XQ |
| 4652N | PACEMAKER / ANGIOGRAPHY DRAPE - FEMORAL, 75" X 157" | 0748426MI01PD29INZ02H |
| 48527-0 | ANGIO DRAPE - FEMORAL, 75" X 150" | 0748426MI01PD28INZ026 |
| 48615-0 | ANGIO DRAPE - FEMORAL, 86' X 135" | 0748426MI01PD28INZ026 |
| 48668-0C | PACEMAKER / ANGIOGRAPHY DRAPE - FEMORAL, 75" X 125" | 0748426MI01PD28INZ026 |
| 48681-0 | PACEMAKER DRAPE, 75" X 110" | 0748426MI01PD29INZ02H |
| 4950N | PATIENT DRAPE IRRIGATION POUCH, 20" X 20" | 0748426MI01PD30INZ0XQ |
| 5960N | PATIENT ISOLATION DRAPE, 96" X 130" | 0748426MI01PD28INZ026 |
| 6017N | TRIANGULAR POUCH WITH FILTER, 24" X 31" | 0748426MI01PD30INZ0XQ |
| 6960N | PATIENT ISOLATION DRAPE, 130" X 96" | 0748426MI01PD28INZ026 |
| 8909N | INSTRUMENT POUCH, 18" X 24" | 0748426MI01PD30INZ0XQ |
| 8939N | APERTURE DRAPE, 32" X 24" | 0748426MI01PD29INZ02H |
| AD134N | ANGIO DRAPE - FEMORAL / RADIAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD200N | ANGIO DRAPE - FEMORAL, 75" X 110" | 0748426MI01PD29INZ02H |
| AD201N | ANGIO DRAPE - FEMORAL, 75" X 125" | 0748426MI01PD29INZ02H |
| AD202N | ANGIO DRAPE - FEMORAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD202NG | ANGIO DRAPE - FEMORAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD206N | ANGIO DRAPE - FEMORAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD215N | MINOR PROCEDURES DRAPE, 38 1/2" X 55" | 0748426MI01PD29INZ02H |
| AD218N | ANGIO DRAPE - FEMORAL, 86" X 158" | 0748426MI01PD29INZ02H |
| AD220N | PEDIATRIC ANGIO DRAPE, 75" X 153" | 0748426MI01PD29INZ02H |
| AD2234N | ANGIO DRAPE - FEMORAL / RADIAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD2234XLN | ANGIO DRAPE - FEMORAL/RADIAL, 86" X 150" | 0748426MI01PD29INZ02H |
| AD2235N | ANGIO DRAPE - FEMORAL / RADIAL, 107" X 135" | 0748426MI01PD29INZ02H |
| AD224-1N | SPECIAL PROCEDURES / ANGIOGRAPHY DRAPE, 86" X 145" | 0748426MI01PD28INZ026 |
| AD228N | ANGIO DRAPE - INTRAJUGULAR / SUBCLAVIAN, 75" X 125" | 0748426MI01PD29INZ02H |
| AD229N | SPECIAL PROCEDURES DRAPE - KYPHO, 75" X 135" | 0748426MI01PD29INZ02H |
| AD230N | PACEMAKER / ANGIO DRAPE - FEMORAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD235N | ANGIO DRAPE - FEMORAL, 86" X 135" | 0748426MI01PD29INZ02H |
| AD248N | ANGIO DRAPE - INTRAJUGULAR/FEMORAL, 75" X 145" | 0748426MI01PD29INZ02H |
| C583324 | DIATHERMY POUCH, 12" X 13" | 0748426MI01PD30INZ0XQ |
| FP5977IN | SHOULDER ARTHROSCOPY POUCH, 30.5" X 33" | 0748426MI01PD30INZ0XQ |
| ISO1000N | Patient Drape ISODrape™ Towel Drape - Small, 46 cm x 30 cm (18 in x 12 in) | 0748426MI01PD30INZ0XQ |
| ISO1010N | ISODRAPE TOWEL DRAPE - LARGE, 18" X 24" | 0748426MI01PD30INZ0XQ |
| ISO1015N | ISODRAPE U DRAPE, 48" X 48" | 0748426MI01PD30INZ0XQ |
| ISO1016N | ISODRAPE IRRIGATION POUCH, 20" X 23" | 0748426MI01PD30INZ0XQ |
| ISO1018N | ISODRAPE INSTRUMENT POUCH DRAPE, 7" X 12" | 0748426MI01PD30INZ0XQ |

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| ISO1019N | ISODRAPE U DRAPE - LONG, 48" X 72" | 0748426MI01PD30INZ0XQ |
| ISO1020N | ISODRAPE APERTURE DRAPE - SMALL, 16" X 16" | 0748426MI01PD29INZ02H |
| ISO1050N | ISODRAPE INCISE DRAPE, 36" X 18" | 0748426MI01PD28INZ026 |
| ISO1051N | ISODRAPE INCISE DRAPE, 36" X 36" | 0748426MI01PD28INZ026 |
| ISO1061N | ISODRAPE APERTURE DRAPE - MEDIUM, 48" X 51" | 0748426MI01PD28INZ026 |
| ISO1071N | ISODRAPE UROLOGICAL DRAPE, 24" X 36" | 0748426MI01PD29INZ02H |
| PD107N | PACEMAKER DRAPE, 75" X 135" | 0748426MI01PD29INZ02H |
| PD200N | PACEMAKER DRAPE, 75" X 125" | 0748426MI01PD29INZ02H |
| PD201N | PACEMAKER DRAPE, 86" X 135" | 0748426MI01PD29INZ02H |
| PD202-1N | PACEMAKER DRAPE, 86" X 135" | 0748426MI01PD28INZ026 |
| PD212-1N | PACEMAKER DRAPE, 100" X 144" | 0748426MI01PD28INZ026 |
| SPD104N | SPECIAL PROCEDURE DRAPE, 43" X 45" | 0748426MI01PD29INZ02H |
| SPD212N | FISTULAGRAM DRAPE, 45" X 60" | 0748426MI01PD29INZ02H |
| SPD2317N | CENTRAL LINE/PICC DRAPE, 77" X 120" | 0748426MI01PD29INZ02H |