# DECLARATION OF CONFORMITY

*We*

| | |
|---|---|
| Name + address of manufacturer: | **Microtek Medical, Inc.**<br>**602 Lehmberg Road**<br>**Columbus, MS 39702**<br>**U.S.A.** |

| | |
|---|---|
| European Representative: | **Microtek Medical BV**<br>**Hekkehorst 24**<br>**7207 BN Zutphen**<br>**The Netherlands** |

*Declare on our own responsibility that*

| | |
|---|---|
| The medical device: | Name<br>**Equipment Drapes** |
| Type: | **See attached list** |
| Class:<br>According to: | **I Sterile**<br>**Rule 1** |

*Meets all the provisions of the Medical Device Directive 93/42/EEC*

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|---|---|---|
| Applied harmonized standards: | EN ISO 13485<br>EN ISO 14971<br>EN ISO 11607-1<br>EN ISO 11607-2<br>EN ISO 10993-1<br>EN ISO 10993-5<br>EN ISO 10993-7 | EN ISO 11135-1<br>EN ISO 11137-1<br>EN ISO 11137-2<br>EN 556-1<br>EN ISO 11737-1<br>EN ISO 11737-2<br>EN 62366<br><br>All applicable standards have been applied. |
| Notified body: | TÜV NORD CERT GmbH<br>Langemarckstr. 20<br>D-45141 Essen<br><br>**CE 0044** | |
| Conformity assessment procedure: | 93/42/EEC<br>Annex V<br>CE Certificate No. 44 237 117845 | |
| Validity: | 14 August 2023 | |
| Place / Date :<br>St. Paul, MN USA<br>29 November 2018 | Name and Function:<br><br>Annemarie Erickson<br>Sr. Regulatory Affairs Manager | |

## DECLARATION OF CONFORMITY

| Row Labels | Part Number | Part Description | Sterilization Method |
|---|---|---|---|
| General Purpose - C-Arm | 2951UK | * ONE PIECE C-ARM DRAPE | ETO |
| | C9-106MEU | MINI C-ARM DRAPE FOR OEC 6600 | ETO |
| | C9-108M | MINI C-ARM DRAPE FOR OEC 6800, 54" X 84" | GAMMA |