

Date: 06/16/2022

LATEX, PHTHALATES AND DEHP FREE STATEMENT

To Whom It May Concern;

The below-listed products (Appendix A) are disposable devices, disposable devices/trays, Surgical devices, and Respiratory care devices manufactured and distributed by Thomas Medical Products Inc. These products do not contain Latex, Phthalates, and DEHP in either the product ingredients or the packaging. As such, the material can be declared free of Bovine Spongiform Encephalopathy (**BSE**) and Transmissible Spongiform Encephalopathy (**TSE**).

The product does not come in contact with any of the above materials throughout the manufacturing process.

Amar Agadi

Dr. Amar Agadi, M.D.
Chief Medical Officer
VP – Operations/QA/Regulatory Affairs

Appendix A – List of Products

TMI1155	Disposable Device	FLEXIBLE CATHETER,HSG, SIS, SHG 7FR, 28CM
TMI1154	Disposable Device	FLEXIBLE CATHETER,HSG, SIS, SHG 5FR, 28CM
TMI1157	Disposable Device/Tray	HSG TRAY
TMI1160	Disposable Device/Tray	TRAY,CATHETER,HSG WITH HS 5FR.COMBO
TMI1161	Disposable Device/Tray	TRAY,CATHETER,HSG WITH HS 7FR.COMBO
TMI1185	Disposable Device	SHAPEABLE CATHETER,HSG, SIS. SHG 5FR, 28CM
TMI1187	Disposable Device	SHAPEABLE CATHETER,HSG, SIS, SHG 7FR, 28CM
TMI2002	Disposable Device	MILLER ADVANCE HSG CATHETER, 5Fr, 28 CM
TMI1188	Disposable Device	STEEN OPEN-TIP CATHETER, HSG, 5FR, 28CM
TMI1198	Disposable Device/Tray	TRAY, SHAPEABLE HSG CATHETER, 5FR,COMBO
TMI1199	Disposable Device/Tray	TRAY, SHAPEABLE HSG CATHETER, 7FR,COMBO
TMI1162-HF	Disposable Device	EZINJECT HF SHG CATHETER, 30CM
TMI1151	Surgical Device	UTERINE MANIPULATOR FRENCH SIZE: 4.5MM/13.5FR
TMI6003	Surgical Device	KRONNER UTERINE MANIPULATOR/INJECTOR - 5MM/15Fr
TMI-ET1	Respiratory Care	ENDOTRACHEAL TUBE HOLDER, DISPOSABLE USED WITH VENTILATORS
LE-04-105	Surgical Device	10 x 5MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-05-101	Surgical Device	10 x 10MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-07-158	Surgical Device	15 X 8MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM

LE-26-150	Surgical Device	15 X10MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-09-208	Surgical Device	20 X 8MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-24-201	Surgical Device	20 x 10MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-11-205	Surgical Device	20 x 15MM LOOP ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-06-108	Surgical Device	10 x 8MM SQUARE ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-06-101	Surgical Device	10 x 10MM SQUARE ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-13-003	Surgical Device	3MM BALL ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM
LE-14-005	Surgical Device	5MM BALL ELECTRODE, TUNGSTEN WIRE, STANDARD SHAFT LENGTH 13CM