

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 18-1616-M

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions: **Canada**: Medical Devices Regulations – Part 1- SOR/98-282.

MAJnMAR Medical Products
203-1130 Austin Avenue
Coquitlam, BC V3K 3P5, Canada

Facility ID: **F001160**

Additional sites covered by QM System: **See Annex 1**

List of Products: **See Annex 2**

Scope:

**Design, Development and Manufacturing of Disposable and Reusable
Trocars, Laparoscopic Instruments, Surgical Devices, Surgical
Staplers, Silicone Drainage System, Sponge Laparotomy, Gauze, EVA
Parenteral Nutrition Infusion Sets**

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **20-3894 SA1-SA4**

Initial Certification Date: **2018-10-30**

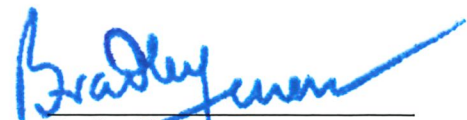
Current Cycle Start Date: **2021-10-27**

Effective Date:

2022-11-03 / ed. 3

Valid Until:

2024-10-29



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 18-1616-M / ed. 3
Company Name: MAJnMAR Medical Products
Central (HQ) Office Address: 203-1130 Austin Avenue
Coquitlam, BC V3K 3P5, Canada



Location

Scope of Certification

Facility ID: F001160 (Campus)

Headquarters

MAJnMAR Medical Products
203-1130 Austin Avenue
Coquitlam, BC V3K 3P5, Canada

Design and development, purchasing,
storage

Site 1

MAJnMAR Medical Products
EN193-163 Schoolhouse Street
Coquitlam, BC V3K 4X8, Canada

Storage

---End of list---

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Annex 2, page 1 of 2

(Annex 2 MUST be displayed with the main certificate)

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Company Name: MAJnMAR Medical Products
Central (HQ) Office Address: 203-1130 Austin Avenue
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Products	UMDNS	GMDN
Surgical Devices		
- Trocars	N/A	42412
- Disposable Endoscopic Veress Needle	N/A	46328
- Disposable Endoscopic Retrieval Bag	N/A	45130
- Disposable Endoscopic Blunt Tip Dissector	N/A	47415
- Disposable Endoscopic Suction-Irrigation Tube	N/A	64120
Disposable and Reusable Endoscopic and Open Surgical Instruments		
- Graspers, Dissectors, Forceps	N/A	47415
- Knot Pusher	N/A	45717
- Needle Holder	N/A	12726
- Clip Appliers, Clips	N/A	65058
- Coagulation Electrodes	N/A	64246
- Camera Sleeve	N/A	12535
Silicone Drainage System		
- Close Wound Drainage System	N/A	11305
- Reservoirs	N/A	11301

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Products	UMDNS	GMDN
Surgical Staplers		
- Endoscopic Linear Cutter and Reloads	N/A	59871/35615
- Linear Cutters and Reloads	N/A	59870/35615
- Linear Staplers and Reloads	N/A	59873/35615
- Circular Staplers	N/A	59875
- Hemorrhoids Staplers	N/A	46737
- Endoscopic Clip Applier	N/A	65721
- Endo Suture	N/A	57874
- Skin Staplers	N/A	35884
- Endoscopic Hernia Stapler	N/A	62844
Swabs		
- Gauze	N/A	48131
- Sponge Laparotomy	N/A	39404
EVA Parenteral Nutrition Infusion Set		
- TPN EVA Bag	N/A	11675

---End of list---

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