

## Certificate

acc. to ISO 13485:2016

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: 18-1617-Q

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 for Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes.

MAJnMAR Medical Products 203-1130 Austin Ave., Suite 203 Coquitlam, BC V3K 3P5 Canada

Additional sites covered by QM System: See Annex

## Scope:

Design, Development, and Manufacture of Disposable and Reusable Trocars, Laparoscopic Instruments, Surgical Devices, Surgical Staplers, and Silicone Drainage System

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

TUV USA, Inc. (A Member of TUV 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



Audit Report Reference No.: 18-8074 CA Certificate Initial Issue Date: 30-OCT-2018

Certificate Revised Date: N/A

Effective Date: 30-OCT-2018 / ed. 1

Valid Until: 29-OCT-2021

Bradley Chen

Director, Medical Products Division

TUV USA, Inc.



Annex 1, page 1 of 1

(Annex 1 MUST be displayed with the main certificate)

Certificate Registered No.: 18-1617-Q / ed. 1

Company name: MAJnMAR Medical Products

Central Office Address: 203-1103 Austin Ave., Suite 203, Coquitlam, BC V3K 3P5 Canada

## Additional Site/s covered by the QM System:

Location

Scope

MAJnMAR Medical Products EN193-163 Schoolhouse St.

Coquitlam, BC V3K 4X8 Canada

Storage Only

---End of list---

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SCC Accredited
CB-MS
OCSM
Accredited CCN

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TUV USA, Inc.



Annex 2, page 1 of 2

(Annex 2 MUST be displayed with the main certificate)

Certificate Registration No.: 18-1616-M / ed. 1 Company Name:

MAJnMAR Medical Products

Central Office Address:

203-1130 Austin Ave., Suite 203, Coquitlam, BC V3K 3P5 Canada

Products		UMDNS	GMDN	
Surgical Devices				
-	Trocars	N/A	42412	
-	Disposable Endoscopic Veress Needle	N/A		
-	Disposable Endoscopic Retrieval Bag	N/A		
-	Disposable Endoscopic Blunt Tip Dissector	N/A		
-	Disposable Endoscopic Suction- Irrigation	N/A		
-	Disposable and Reusable Endo- scopic and Open Surgical Instru- ments: Graspers, Dissectors, Scissors, Forceps, Knot Pusher, Needle Holders, Clip Appliers, Clips, Coagulation Electrodes, Camera Sleeve	N/A		

## ---End of list---

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Bradley Chen
Director, Medical Products Division
TUV USA, Inc.



Annex 2, page 2 of 2

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Certificate Registration No.: 18-1616-M / ed. 1 Company Name: MAJnMAR Medical Products

Central Office Address: 203-1130 Austin Ave., Suite 203, Coquitlam, BC V3K 3P5 Canada

Products	UMDNS	GMDN
Silicone Drainage System - Closed Wound Drainage System - Reservoirs	N/A N/A	11305
Surgical Staplers - Endoscopic Linear Cutter and Reloads	N/A	59871
- Linear Cutters and Reloads	N/A	
<ul> <li>Linear Staplers and Reloads</li> </ul>	N/A	==
<ul> <li>Circular Staplers</li> </ul>	N/A	
<ul> <li>Hemorrhoids Staplers</li> </ul>	N/A	
<ul> <li>Endoscopic Clip Applier</li> </ul>	N/A	58040
<ul> <li>Endo Suture</li> </ul>	N/A	
- Skin Staplers	N/A	
<ul> <li>Endoscopic Hernia Stapler</li> </ul>	N/A	

---End of list---

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