



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 Ave., Suite 203
Coquitlam, BC V3K 3P5 Canada

DUNS number: **203-466-7584**

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

List of Products: *See Annex 2*

**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 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



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 Registration No. : **18-1616-M / ed. 1**

Company Name: **MAJnMAR Medical Products**

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

Location

Scope of Certification

MAJnMAR Medical Products
EN193-163 Schoolhouse St.
Coquitlam, BC V3K 4X8 Canada
DUNS number: **203-466-7584**

Storage Only

---End of list---

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



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 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 Endoscopic and Open Surgical Instruments: Graspers, Dissectors, Scissors, Forceps, Knot Pusher, Needle Holders, Clip Applicators, Clips, Coagulation Electrodes, Camera Sleeve	N/A	--

---End of list---

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



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 2, page 2 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
Silicone Drainage System		
- Closed Wound Drainage System	N/A	11305
- Reservoirs	N/A	--
Surgical Staplers		
- Endoscopic Linear Cutter and Reloads	N/A	59871
- Linear Cutters and Reloads	N/A	--
- Linear Staplers and Reloads	N/A	--
- Circular Staplers	N/A	--
- Hemorrhoids Staplers	N/A	--
- Endoscopic Clip Applier	N/A	58040
- Endo Suture	N/A	--
- Skin Staplers	N/A	--
- Endoscopic Hernia Stapler	N/A	--

---End of list---

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



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.