

Certificate

Management system as per
ISO 13485:2016 (MDSAP)

The Auditing Organization TUV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

MAJnMAR Medical Products
203-1130 Austin Avenue
Coquitlam, British Columbia V3K 3P5
Canada
[Facility ID: F001160]

With „Additional Sites“ according to the annex 1
With „Products“ according to the annex 2

Operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for the following jurisdictions:
Canada: Medical Devices Regulations – Part 1- SOR/98-282.

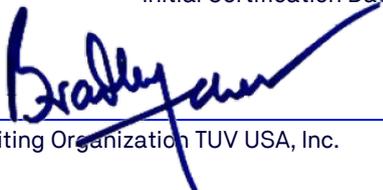
Scope

Design, Development, and Manufacture of Surgical Devices, Disposable and Reusable Endoscopic and Open Surgical Instruments, Silicone Drainage System, Surgical Staplers, and Swabs

Certificate Registration No. 24-1628-M
Project No. 24-4122 RC-CSA

Issue Date: 2024-10-30
Reissue Date: 2024-10-15
Expiry Date: 2027-10-29
Initial Certification Date: 2018-10-30

Salem, NH; 2024-10-15, Edition 1


Auditing Organization TUV USA, Inc.

The validity of this certificate may be obtained by contacting TUV USA at: +1 (603) 870-8023 (option 1) or via Email: medical-usa@tuv-nord.com

TUV USA, Inc.
215 Main Street, Salem, NH 03079
United States of America
www.tuv-nord.com/us
TÜV ®



TUV USA, Inc. is recognized under the Medical Device Single Audit Program

Annex 1

to Certificate Registration No. 24-1628-M
ISO 13485:2016 (MDSAP)

MAJnMAR Medical Products
203-1130 Austin Avenue
Coquitlam, British Columbia V3K 3P5
Canada
[Facility ID: F001160]

Validity of Annex depends on the validity of the main certificate.

Certificate Registration No.	Location	Scope
24-1628-M [Facility ID: F001160]	MAJnMAR Medical Products 203-1130 Austin Avenue Coquitlam, British Columbia V3K 3P5 Canada	Headquarters Design, Development, and Sales
24-1628-M-001 [Facility ID: F001160]	MAJnMAR Medical Products EN193-163 Schoolhouse Street Coquitlam, British Columbia V3K 4X8 Canada	Storage

End of the List

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Annex 2

to Certificate Registration No. 24-1628-M
ISO 13485:2016 (MDSAP)

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Products	UMDNS	GMDN
Surgical Devices Surgical Devices		
- Trocars	N/A	42412
- Disposable Endoscopic Veress Needle	N/A	46328
- Disposable Endoscopic Retrieval Bag	N/A	45130
- Disposable Endoscopic Suction-Irrigation Tube	N/A	64120
Disposable and Reusable Endoscopic and Open Surgical Instruments		
- Graspers, Dissectors, Forceps	N/A	47415
Silicone Drainage System		
- Close Wound Drainage System	N/A	11305
- Reservoirs	N/A	11301
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	49737
- Endoscopic Hernia Staplers	N/A	62844
- Power Staplers	N/A	59871
Swabs		
- Gauze	N/A	48131
- Sponge Laparotomy	N/A	39404

End of the List

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