Accreditations & Registrations

TME implements a Quality Management System through its organizational structure, responsibilities, procedures, processes and resources.

These measures are the guidance to all our personnel involved in activities and are provided in accordance with customer requirements and applicable legal regulations in Saudi Ara

KINGDOM OF SAUDI ARABIA
Saudi Food & Drug Authority
Operations Sector

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
قطاع العمليات

VISION 2030 رؤية

Executive Department of registration and licensing

الإدارة التنفيذية للتسجيل والتراخيص

رخصة ممثل قانوني
Authorised Representative License

Issuing Authority: Saudi Food And drug Authority. جهة الاصدار: الهيئة العامة للغذاء والدواء

Enabling Legislation: Medical Device Interim Regulation supported by Implementing Rule MDS-IR5 on Licensing of Authorised Representatives. المرجع القانوني: لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية (IR5-MDS) الخاصة بترخيص الممثل القانوني.

Licensed Activity: acting on behalf of the MANUFACTURER for the medical device within the KSA according to the AR agreement with the exception to the paragraph pertaining additional tasks and Provisions. نشاط المنشأة: التمثيل القانوني للمصنع داخل المملكة العربية السعودية وفق لاتفاقية التمثيل القانوني فيما عدا المادة الخاصة بالمهام والأحكام الاضافية الاختيارية.

أصدرت رخصة ممثل قانوني لـ: مؤسسة الطيب الطبية للتجارة

An Authorised Representative license has been issued to: AlTayeb Medical Trading EST

License Number: ARL-2020-MD-3570 رقم الرخصة بالنظام:

MANUFACTURER: Chongqing Jinshan Science & Technology (Group) Co. Ltd. المصنّع:

Account number for AR: C-1769 رقم الحساب للممثل القانوني:

Issuing date/ Expiry date: 24/8/2020 - 21/8/2023 تاريخ الاصدار / تاريخ الانتهاء:

Issuance Type: Renew نوع الاصدار: تجديد

Device category(ies): 1. Single-use Devices أصناف الأجهزة والمنتجات الطبية:

Establishments Licensing Department Director مدير إدارة تراخيص المنشآت

م. أحمد بن عبدالله رجب

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KINGDOM OF SAUDI ARABIA
Saudi Food & Drug Authority

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

VISION 2030 رؤية

Executive Department of Medical Devices Evaluation
Medical Devices And Products Sector

الإدارة التنفيذية لتقييم الأجهزة الطبية
قطاع الأجهزة و المنتجات الطبية

إذن تسويق جهاز / منتج طبي
Medical Device Marketing Authorisation

Issuing Date: 03/1/2018 **Authorization Number:** GHTF-2018-2793 رقم الإذن: تاريخ الإصدار: 16/4/1439

Expiry Date: 24/5/2024 **Version Number:** 6 رقم الإصدار: تاريخ الانتهاء: 17/11/1445

Last Version Date: 20/9/2021 تاريخ آخر إصدار: 13/2/1443

The authorisation is issued in accordance with the Medical devices interim regulation (MDIR) and in particular to the implementing rule MDS-IR6 for Medical Device Marketing Authorisation (MDMA)

أصدر هذا الإذن بموجب لائحة رقابة الأجهزة والمنتجات الطبية والقواعد الإجرائية (MDS-IR6) الخاصة بإذن تسويق الأجهزة والمنتجات الطبية.

This authorization allows:

ME0000008809
Micro-Tech (Nanjing) Co., Ltd
No. 10, Gaoke Third Road, Nanjing National Hi-Tech Industrial Development Zone, Nanjing,Jiangsu,210032 China

هذا الإذن يخول:

To market the medical devices listed in the attached annex* in the Kingdom of Saudi Arabia

بتسويق الأجهزة / المنتجات الطبية المحددة في القائمة المرفقة* في المملكة العربية السعودية

المدير التنفيذي لتقييم الأجهزة الطبية
Executive Director of Medical Devices Evaluation

د.عبد اللطيف بن سليمان الوطبان
Abdullatif S.Al Watban,Ph.D.

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NEUTRAL VERITAS TRANSPARENT

Certificate of Registration

Certificate No: 221130066603

This is to Certify that

ALTAYEB MEDICAL TRADING EST

3035 Hira – Ash Shati Dist, Jeddah 7580 - 23513, Kingdom of Saudi Arabia

Operate a Quality Management System which complies with the requirement of

ISO 13485:2016

(Medical Device – Quality Management System)

For the following Scope

Importing, Sales, Distribution of Medical Accessories of Endoscopic gastrointestinal, Urological and surgical Products

Initial Registration Date	**30th Nov. 2022**	**Current Issue Date**	**30th Nov. 2022**
1st Surveillance on or before	**30th Oct. 2023**	**Valid Until**	**29th Nov. 2023**
2nd Surveillance on or before	**30th Oct. 2024**	**Revision**	**00**

Certification Cycle of this certificate is three (3) years from the issue date and validity of the certificate shall be subject to the successfully completion of the surveillance audit as mentioned above, current Status of Certificate can be verified on i.e. www.isoindia.org & www.iafcertsearch.org

UNITED ACCREDITATION FOUNDATION UAF
MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CB-MS-2207

Pragyesh Singh, CEO
TNV Certification Pvt Ltd
CIN: U74900UP2011PTC046719
Accredited by United Accreditation Foundation (UAF)

Accreditation Board Add.: United Accreditation Foundation Inc, 400 North Center Dr Ste 202, Norfolk, Va 23502, United States of America

Certification Body Add. H.O.: TNV House, 537-B/187-B, Amber Vihar, Lucknow-20 India, Mail: info@isoindia.org

* Validity of this certificate is subject to continued compliance of the management system standard and successful completion of audit as planned by TNV from time to time. Further clarification regarding the scope of this certificate and the applicability of standard may be obtained by consulting the organisation. This certificate remains property of the TNV and must be returned on request. For surveillance details, please visit at www.isoindia.org. Regd. office of the TNV is TNV House, B-1/1/68, Sec-K, Aliganj, Lucknow-24, UP, India