



Reg. No. 305/Q-054

CERTIFICATE

*This certifies that the Quality management system for medical devices
of company*

Healthium Medtech Limited

No. 472/D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka - 560 058, India
Manufacturing Site 1: No. 472/D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore,
Karnataka - 560 058, India



*has been assessed by 3EC International
and found to be in conformance with the following standard:*

ISO 13485:2016 / EN ISO 13485:2016

for the following scope:

DESIGN, MANUFACTURE, SALES AND DISTRIBUTION OF NON-ACTIVE STERILE MEDICAL DEVICES,
DEVICES FOR WOUND CARE, ABSORBABLE SURGICAL SUTURES AND NON ABSORBABLE
ATTACHED WITH ATRAUMATIC NEEDLE OR WITHOUT NEEDLE,
ABSORBABLE HEMOSTAT, CARDIAC PACING WIRES, SURGICAL MESHES, BONE WAX, STERILE SKIN
STAPLER, SKIN STAPLES REMOVER, ENDO STAPLERS, KNOTLESS TISSUE CLOSURE DEVICES,
SURGICAL NEEDLE-SPRING EYE, UMBILICAL COTTON TAPE, WOUND DRESSING AND LIGATING CLIPS

DESIGN AND DEVELOPMENT, MANUFACTURE, SALES AND DISTRIBUTION OF NON-ACTIVE
STERILE AND NON-STERILE ARTHROSCOPY PRODUCTS (IMPLANTS AND INSTRUMENTS)

MANUFACTURE, SALES AND DISTRIBUTION OF NON-ACTIVE NON-STERILE SEMI-FINISHED
ARTHROSCOPY IMPLANTS AND INSTRUMENTS

SALES AND DISTRIBUTION OF ACTIVE NON-STERILE ARTHROSCOPY EQUIPMENT'S
SERVICE OF ACTIVE AND NON-ACTIVE ARTHROSCOPY INSTRUMENTS AND EQUIPMENT'S

DESIGN AND DEVELOPMENT, MANUFACTURING, SALES AND DISTRIBUTION, SERVICE OF ACTIVE
ARTHROSCOPY EQUIPMENT'S

MANUFACTURE SALES AND DISTRIBUTION OF NON-STERILE LIGATING CLIP APPLIER AND NON-ACTIVE STERILE
FOLEY BALLOON CATHETER 2 WAYS AND 3 WAYS AND NON-ACTIVE STERILE DISPOSABLE TROCAR

Certificate No.: M-0510A/24

Date of issuance: July 10th, 2024

Original date of approval: July 22nd, 2021

This certificate is valid from **June 22nd, 2024** to **July 21st, 2027** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic




Dr. Katarína Tomín Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.



CERTIFICATE

This certifies that the Quality management system of company

Healthium Medtech Limited

No. 472/D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka - 560 058, India
Manufacturing Site 1: No. 472/D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore,
Karnataka - 560 058, India



*has been assessed by 3EC International
and found to be in conformance with the following standard:*

ISO 9001:2015

for the following scope:

DESIGN, MANUFACTURE, SALES AND DISTRIBUTION OF NON-ACTIVE STERILE MEDICAL DEVICES,
DEVICES FOR WOUND CARE, ABSORBABLE SURGICAL SUTURES AND NON ABSORBABLE
ATTACHED WITH ATRAUMATIC NEEDLE OR WITHOUT NEEDLE,
ABSORBABLE HEMOSTAT, CARDIAC PACING WIRES, SURGICAL MESHES, BONE WAX, STERILE SKIN
STAPLER, SKIN STAPLES REMOVER, ENDO STAPLERS, KNOTLESS TISSUE CLOSURE DEVICES,
SURGICAL NEEDLE-SPRING EYE, UMBILICAL COTTON TAPE, WOUND DRESSING AND LIGATING CLIPS

DESIGN AND DEVELOPMENT, MANUFACTURE, SALES AND DISTRIBUTION OF NON-ACTIVE
STERILE AND NON-STERILE ARTHROSCOPY PRODUCTS (IMPLANTS AND INSTRUMENTS)

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ARTHROSCOPY IMPLANTS AND INSTRUMENTS

SALES AND DISTRIBUTION OF ACTIVE NON-STERILE ARTHROSCOPY EQUIPMENT'S
SERVICE OF ACTIVE AND NON-ACTIVE ARTHROSCOPY INSTRUMENTS AND EQUIPMENT'S

DESIGN AND DEVELOPMENT, MANUFACTURING, SALES AND DISTRIBUTION, SERVICE OF ACTIVE
ARTHROSCOPY EQUIPMENT'S

MANUFACTURE SALES AND DISTRIBUTION OF NON-STERILE LIGATING CLIP APPLIER AND NON-ACTIVE STERILE
FOLEY BALLOON CATHETER 2 WAYS AND 3 WAYS AND NON-ACTIVE STERILE DISPOSABLE TROCAR

Certificate No.: Q-0868/24

Date of issuance: July 10th, 2024

Original date of approval: July 22nd, 2021

This certificate is valid from July 22nd, 2024 to July 21st, 2027 on condition that organization will maintain effective
Quality management system. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic



Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-050 with accreditation
certificate No. Q-050 for certification of Quality management systems covered by EA MLA and IAF MLA.