



<u>USNAS</u> Reg. No. 305/Q-050

## CERTIFICATE

This certifies that the Quality management system of company

## **Healthium Medtech Limited**

No. 472 D, 13th Cross, 4th Phase, Péenyç1 Industriai Area, 560 058 Bangalore, Kamataka, India Site 1: #472-D 13TH éROSS, 4TH PHASE, PEENYA INDUSTRIALAREA, BANGALQRE, KI\RNATAKA-560058, INDIA

has been assessed by 3EC International and found to be in col)forntance with the following standard:

ISO 9001:2015

tor the following scope:

DESIGN, MANUFACTURE ANO. SALTS OF NQN-ACTIVE STERILE MEDICAL DEVICES, DEVICES- FOR WOIJND CARE; .ABSORBABLE AND, NQN ABSORBABLE SURGICAL SUTURES AT; rACHEÒ WITH ATRAUMATIE NEEOLE OR WJTHOUT NEEDLE, ABSORBABLE HEMOSTAT, J"EMPORARY CARDIAC PACING WIRES, SURGICAL MESHES, BONE, WAX, STERILE SKI STAPLER, SKIN STAPLES REMOVER, ENDO STAPLERS, KNOTLESS TISSUE CLOSURE DEVICES, LIGATING CLIPS, SURGICAL NEEDLE -SPRING EYE AND UMBILICAL COTTON TAPE

Certificate No.: Q--0868A/21

Date of issuance: August 6th, 2021

Originai c;late of approva1: July 22.nd, 202-1

This certificate is valid from August 6th, 2021 to July 21st, 2024 on conditic;m 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.

This certificate fully super.sedes previous certificate No. Q-0868121 issliecion .July 22nd; 202t.

Issuing office: 3EC InternationaJ a.s., Hranicna 18, 821 05 Bratislava, Slovak Repùblic

or. Katarina Tomin Srdošová

Head of Certification Body 3EC International a.s.

Certificatron body 3ÈC International a.s, is accredited by SNAS under registration number 305/Q-050 With accreditation certificate No. Q-050 lor certification of Quarity management systems covered by EA MLA and IAF MLA.

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## **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, 560 058 Bangalore, Karnataka, India Site 1: #472-D, 13TH CROSS, 4TH PHASE, PEENYA INDUSTRIAL AREA, BANGALORE, KARNATAKA-560058, INDIA

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

EN ISO 13485:2016

for the following scope:

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

Certificate No.: M-0510A/21

Date of issuance: August 6th, 2021

Original date of approval: July 22nd, 2021

This certificate is valid from August 6th, 2021 to July 21st, 2024 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.

This certificate fully supersedes previous certificate No. M-0510/21 issued on July 22nd, 2021.

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

Or. Katarina Tomin Śrdošová

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