3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2022-MDR/QS-011

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andra Pradesh – 517 646, India
SRN No.: IN-MF-000008421
Name and adress of the Authorized representative:
MED DEVICES LIFESCIENCES B.V., Keizersgracht 482, 1017 EG Amsterdam, The Netherlands

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:
MONOFILAMENT POLYPROPYLENE
STERILE NON-ABSORBABLE SURGICAL SUTURE
(for detailed list refer to Annex I)
Intended purpose: Annex II
MD class III

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR026_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR026_2021 from August 4, 2022 and MD Audit Report No. SK-0643-22 from August 4, 2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **August 15, 2022**
Valid until: **August 15, 2027**
First issue: **August 15, 2022**
Revision: **00**
History: **Annex III**

In Bratislava, Slovakia, August 15, 2022

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-011

issued for the company

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andra Pradesh – 517 646, India

List of medical devices covered by the EU Quality Management System Certificate:

MONOFILAMENT POLYPROPYLENE

STERILE NON-ABSORBABLE SURGICAL SUTURE

Brand Name	USP sizes	EP metric size
TRULENE, VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE, ALPHA-LENE, LINX PROLINE, LENE POLYPROPYLENE, Q-CLOSE POLYP, U-LENE, MOPYLEN, MOPYLEN CV, SURGISUT TRULENE, B- LENE,TRUVET POLYPROPYLENE, IM- LENE, EPYLENE, UNODENT POLYPROPYLENE, PROPYLCUT, N-CARE POLYPROPYLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3&4	0.2, 0.3, 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6

* Suture is supplied with or without needles.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, August 15, 2022
Valid until August 15, 2027

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-011

issued for the company

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andra Pradesh – 517 646, India

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Monofilament Polypropylene suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological tissues.

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, August 15, 2022
Valid until August 15, 2027

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-011

issued for the company

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andra Pradesh – 517 646, India

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-011	15.8.2022	MDR026_2021	Initially granted certification

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, August 15, 2022
Valid until August 15, 2027

3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-011

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India
Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andhra Pradesh – 517 646, India
SRN No.: IN-MF-000008421
Name and address of the Authorized representative:
MED DEVICES LIFESCIENCES B.V., Keizersgracht 482, 1017 EG Amsterdam, The Netherlands

This EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that technical documentation of the medical device:
MONOFILAMENT POLYPROPYLENE
STERILE NON-ABSORBABLE SURGICAL SUTURE
(for detailed list refer to Annex I)
Intended purpose: Annex II
MD class III
Basic UDI-DI: 8903837H010201010426

meets the requirements of technical documentation assessment according to the Chapter II Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed technical documentation assessment of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the technical documentation assessment of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR026_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR026_2021 from August 4, 2022 and MD Audit Report No. SK-0643-22 from August 4, 2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Technical Documentation Assessment Certificate** applies only to the abovementioned medical device. For the placing on the market of the MDs which this certificate covers, the EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **October 18, 2022**
Valid until: **August 15, 2027**
First issue: **August 15, 2022**
Revision: **01**
History: **Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, October 18, 2022

ANNEX I TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-011

issued for the company

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andhra Pradesh – 517 646, India

List of medical devices covered by the EU Technical Documentation Assessment Certificate:

MONOFILAMENT POLYPROPYLENE **STERILE NON-ABSORBABLE SURGICAL SUTURE**		
Brand Name	**USP sizes**	**EP metric size**
TRULENE, VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE, ALPHA-LENE, LINX PROLINE, LENE POLYPROPYLENE, Q-CLOSE POLYP, U-LENE, MOPYLEN, MOPYLEN CV, SURGISUT TRULENE, B- LENE,TRUVET POLYPROPYLENE, IM- LENE, EPYLENE, UNODENT POLYPROPYLENE, PROPYLCUT, N-CARE POLYPROPYLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3&4	0.2, 0.3, 0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5, 6

* Suture is supplied with or without needles.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, October 18, 2022
Valid until August 15, 2027

ANNEX II TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-011

issued for the company

Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore, Karnataka – 560 058, India

Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andhra Pradesh – 517 646, India

Intended purpose of medical devices covered by the EU Technical Documentation Assessment Certificate:

Monofilament Polypropylene suture is intended for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological tissues.

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, October 18, 2022
Valid until August 15, 2027

ANNEX III TO EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-011

issued for the company

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Manufacturing Site 02: Plot No: 1605, Portia Road, Sri City, Tirupati District, Andhra Pradesh – 517 646, India

Certificate history:

Revision	EU TD Assessment Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/TD-011	15.8.2022	MDR026_2021	Initially granted certification
01	2022-MDR/TD-011	18.10.2022	MDR026_2021	Correction of typo mistake in the manufacturing site 02 address

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, October 18, 2022
Valid until August 15, 2027