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

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
# No. 2022-MDR/QS-017

## 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:
**STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE MESH**
**(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. MDR034_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR034_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**

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

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

In Bratislava, Slovakia, August 15, 2022

# ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-017

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:**

| **STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE MESH** | |
|---|---|
| **Brand Name** | **Sizes (cm)** |
| TRULENE MESH, ALPHA-LENE MESH, LINX REGULAR MESH, LINX LIGHT MESH, Q-CLOSE MESH, SURGISUT TRULENE MESH, IM -LENE MESH, LINX LAPRO MESH, B-LENE MESH, RESORBA PP MESH, D·TEK POLYPROPYLENE MESH, TRULENE MACROPORE MESH, TRULENE SOFT MESH, TRULENE LAPARO MESH | Length: 1 to 30<br>Width: 1 to 30 |



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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-017

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:**

Sterile Non-Absorbable Surgical Polypropylene Mesh is intended for use in repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.



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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-017

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-017 | 15.8.2022 | MDR034_2021 | Initially granted certification |



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Katarína Tomin Srdošová, PhD.
*Director of NB2265*

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

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international

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

# EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-017

## 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:
**STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE MESH**
**(for detailed list refer to Annex I)**
**Intended purpose: Annex II**
**MD class III**
**Basic UDI-DI: 8903837P900202FY**

**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. MDR034_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR034_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**

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**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-017

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:**

| **STERILE NON-ABSORBABLE SURGICAL POLYPROPYLENE MESH** | |
|---|---|
| **Brand Name** | **Sizes (cm)** |
| TRULENE MESH, ALPHA-LENE MESH, LINX REGULAR MESH, LINX LIGHT MESH, Q-CLOSE MESH, SURGISUT TRULENE MESH, IM -LENE MESH, LINX LAPRO MESH, B-LENE MESH, RESORBA PP MESH, D·TEK POLYPROPYLENE MESH, TRULENE MACROPORE MESH, TRULENE SOFT MESH, TRULENE LAPARO MESH | Length: 1 to 30<br>Width: 1 to 30 |



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-017

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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:**

Sterile Non-Absorbable Surgical Polypropylene Mesh is intended for use in repair of abdominal wall hernias and abdominal wall deficiencies that require the addition of a reinforcing material to obtain the desired surgical result.



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-017

issued for the company

## Healthium Medtech Limited

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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-017 | 15.8.2022 | MDR034_2021 | Initially granted certification |
| 01 | 2022-MDR/TD-017 | 18.10.2022 | MDR034_2021 | Correction of typo mistake in the manufacturing site 02 address |



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Katarína Tomin Srdošová, PhD.
*Director of NB2265*

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