



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

## EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-007

### 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 address 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 POLYDIOXANONE**

**STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE**

(for detailed list refer to Annex I)

Intended purpose: Annex II

MD class III

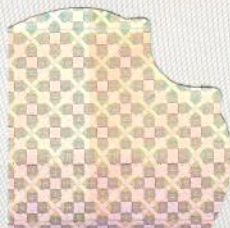
meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

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. MDR022\_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR022\_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**



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-007

issued for the company

### Healthium Medtech Limited

Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,  
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517 646, India

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

##### MONOFILAMENT POLYDIOXANONE

##### STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE

Brand Name	USP sizes	EP metric size
PD SYNTH, VETSUTURE PDX, NOÉCARE PDX, NOÉDENTAL PDX, LINX PDO, PDX POLYDIOXONONE, Q-CLOSE PDSYNTH, PDO RESORBA, U- PD SYNTH, SURGISUT PD SYNTH, B-PD SYNTH, TRUVET POLYDIOXANONE, IM- PDS, EXANONE, UNODENT PDO, N-CARE PD SYNTH, ALAN ANONE	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2	0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5

\* Suture is supplied with or without needles.

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Katarina 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-007

issued for the company

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Registered Place of Business: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,  
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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 Polydioxanone suture is intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable. The safety and effectiveness of Monofilament Polydioxanone suture has not been established in neurological tissue, adult cardiovascular tissue and microsurgery.

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Katarina Tomin Srdošová, PhD.  
Director of NB2265

In Bratislava, Slovakia, August 15, 2022  
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## ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-007

issued for the company

### Healthium Medtech Limited

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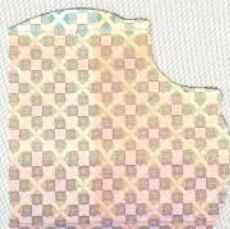
Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore,  
Karnataka – 560 058, India

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-007	15.8.2022	MDR022_2021	Initially granted certification

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Director of NB2265

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





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Notified body No. 2265

## EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-007

### 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 POLYDIOXANONE  
STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE**  
(for detailed list refer to Annex I)  
**Intended purpose:** Annex II  
**MD class** III  
**Basic UDI-DI:** 8903837H0101010101ZC

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. MDR022\_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR022\_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**



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

In Bratislava, Slovakia, October 18, 2022





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517 646, India

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

#### MONOFILAMENT POLYDIOXANONE

#### STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE

Brand Name	USP sizes	EP metric size
PD SYNTH, VETSUTURE PDX, NOÉCARE PDX, NOÉDENTAL PDX, LINX PDO, PDX POLYDIOXONONE, Q-CLOSE PDSYNTH, PDO RESORBA, U- PD SYNTH, SURGISUT PD SYNTH, B-PD SYNTH, TRUVET POLYDIOXANONE, IM- PDS, EXANONE, UNODENT PDO, N-CARE PD SYNTH, ALAN ANONE	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2	0.4, 0.5, 0.7, 1, 1.5, 2, 3, 3.5, 4, 5

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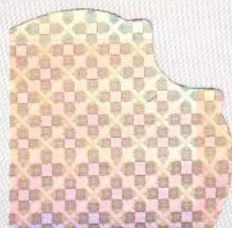
Manufacturing Site 01: No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore,  
Karnataka – 560 058, India

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 Polydioxanone suture is intended for use in general soft tissue approximation, including use in paediatric cardiovascular tissue where growth is expected to occur, and ophthalmic surgery. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable. The safety and effectiveness of Monofilament Polydioxanone suture has not been established in neurological tissue, adult cardiovascular tissue and microsurgery.

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#### Certificate history:

Revision	EU TD Assessment Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/TD-007	15.8.2022	MDR022_2021	Initially granted certification
01	2022-MDR/TD-007	18.10.2022	MDR022_2021	Correction of typo mistake in the manufacturing site 02 address

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