



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-015

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 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:

**BRAIDED AND COATED POLYGLYCOLIC ACID - FAST ABSORBABLE
STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE**

(for detailed list refer to Annex I)

Intended purpose: Annex II

MD class III

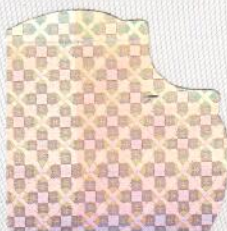
meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

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. MDR032_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR032_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: **October 18, 2022**
Valid until: **August 15, 2027**
First issue: **August 15, 2022**
Revision: **01**
History: **Annex III**

In Bratislava, Slovakia, October 18, 2022



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



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-015

issued for the company

Healthium Medtech Limited

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517 646, India

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

BRAIDED AND COATED POLYGLYCOLIC ACID - FAST ABSORBABLE STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE

Brand Name	USP sizes	EP metric size
TRUGLYDE FAST, LINX RPGA, POLYGLYCOLIC ACID FAST, U-GLYDE FAST, SURGISUT TRUGLYDE FAST, PGA RESOQUICK, TRUVET POLYGLYCOLIC ACID FAST, IM-GLYDE FAST, ESORB PLUS, UNODENT PGA FAST, POGAL FAST, N-CARE PGA FAST, ALAN GLYDE FAST	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, October 18, 2022
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ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-015

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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 Quality Management System Certificate:

Braided and Coated Polyglycolic acid - Fast Absorbable suture is intended for use in general soft tissue approximation where only short term wound support is required and where rapid absorption of the suture would be beneficial. Due to the rapid absorption profile, Braided and Coated Polyglycolic acid - Fast Absorbable suture is useful for skin closure, particularly in paediatric surgery, episiotomies, circumcision and closure of oral mucosa. Braided and Coated Polyglycolic acid - Fast Absorbable suture is also useful for conjunctival suturing in ophthalmic surgery.

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Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, October 18, 2022
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ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-015

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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-015	15.8.2022	MDR032_2021	Initially granted certification
01	2022-MDR/QS-015	18.10.2022	MDR032_2021	Correction of typo mistake in the manufacturing site 02 address

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

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE No. 2022-MDR/TD-015

Healthium Medtech Limited

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

**BRAIDED AND COATED POLYGLYCOLIC ACID - FAST ABSORBABLE
STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE**

(for detailed list refer to Annex I)

Intended purpose: Annex II

MD class III

Basic UDI-DI: 8903837H0101010201ZH

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. MDR032_2021 from August 4, 2022, MD Clinical Evaluation Report No. MDR032_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.



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

BRAIDED AND COATED POLYGLYCOLIC ACID - FAST ABSORBABLE STERILE SYNTHETIC ABSORBABLE SURGICAL SUTURE

Brand Name	USP sizes	EP metric size
TRUGLYDE FAST, LINX RPGA, POLYGLYCOLIC ACID FAST, U-GLYDE FAST, SURGISUT TRUGLYDE FAST, PGA RESOQUICK, TRUVET POLYGLYCOLIC ACID FAST, IM-GLYDE FAST, ESORB PLUS, UNODENT PGA FAST, POGAL FAST, N-CARE PGA FAST, ALAN GLYDE FAST	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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Intended purpose of medical devices covered by the EU Technical Documentation Assessment Certificate:

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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-015	15.8.2022	MDR032_2021	Initially granted certification
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