



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC CERTIFICATE

No. 2017-MDD/QS-055/B

issued in compliance with the Council Directive 93/42/EEC as amended by 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the medical device of Class III,

Sterile Absorbable Surgical Suture with or without needle
Sterile Non-absorbable Surgical Suture with or without needle
Sterile Partially Absorbable Surgical Mesh

(for detailed list refer to Annex; pages 1 to 2)

manufactured by company

Healthium Medtech Private Limited
Plot No. 1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post,
Satyavedu Mandal, Chittoor District, Andhra Pradesh - 517 588, India

is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3, and 5, of the Directive 93/42/EEC as amended by 2007/47/EC. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. 310300 and the Final protocols No. 310300/2017, 310300A/2018 and 310300B/2019.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested. The certificate remains valid until the manufacturing conditions or the quality system are changed but until November 9th, 2022 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfilment of relevant legal and other requirements by manufacturer. For the placing on the market of the above referenced models of medical devices covered by this certificate, an EC design-examination certificate according to the Directive 93/42/EEC as amended by 2007/47/EC, Annex II (4) is required.




Dr. Katarina Tomin Srdošová
Responsible to act on behalf of NB 2265

In Bratislava, on January 21st, 2019
Version B) supersedes the EC Certificate No. 2017-MDD/QS-055/A issued on February 15th, 2018



ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-055/B

issued for the company

Healthium Medtech Private Limited
Plot No. 1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post,
Satyavedu Mandal, Chittoor District, Andhra Pradesh - 517 588, India

List of medical devices covered by the EC Certificate:

Product name: Sterile Absorbable Surgical Suture with or without needle

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Polyglycolic Acid Suture	TRUGLYDE	POGAL, N-CARE PGA, IGLYDE, RITEMED PGA, GEYCOL, ALAN GLYDE, U-GLYDE, PGA RESORBA	9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglycolic Acid Suture (Fast absorbable)	TRUGLYDE FAST	POGAL FAST, N-CARE PGA FAST, RITEMED PGA FAST, GEYCOL FAST, ALAN GLYDE FAST, U-GLYDE FAST, PGA RESOQUICK	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglactin 910 Suture	TRUSYNTH	VETSUTURE PGLA, NOÉCARE PGLA, NOÉDENTAL PGLA, POGAL 910, N-CARE POLYGLACTIN 910, ISYNTH, RITEMED PGLA, GEY910, Q-CLOSE SYNTH, U-SYNTH	9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglactin 910 Suture (Fast absorbable)	TRUSYNTH FAST	VETSUTURE FASTPGLA, NOÉCARE FASTPGLA, NOÉDENTAL FASTPGLA, ALANLACT FAST, POGAL 910 FAST, N-CARE POLYGLACTIN 910 FAST, ISYNTH FAST, RITEMED PGLA FAST, Q-CLOSE SYNTH FAST, U-SYNTH FAST, FYSORB	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polydioxanone Suture	PD SYNTH	VETSUTURE PDX, NOÉCARE PDX, NOÉDENTAL PDX, PDX, N-CARE PD SYNTH, RITEMED POLYDIOXONONE, Q-CLOSE PDSYNTH, ALAN ANONE, PDO RESORBA	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglcaprone 25 Suture	MONOGLYDE	VETSUTURE PGC, NOÉCARE PGC, NOÉDENTAL PGC, POGAL MONO, N-CARE MONOGLYDE, RITEMED POLIGLECAPRONE, GEYCRYL, Q-CLOSE MONO, ALAN GLECA, FYSORB MONO	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2

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ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-055/B

issued for the company

Healthium Medtech Private Limited

Plot No. 1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post,
Satyavedu Mandal, Chittoor District, Andhra Pradesh - 517 588, India

List of medical devices covered by the EC Certificate:

Product name: Sterile Non-absorbable Surgical Suture with or without needle

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Silk Suture	TRUSILK	VETSUTURE SILK, NOÉCARE SILK, NOÉDENTAL SILK, ALAN SILK, SILK CUT, N-CARE SILK, ISILK, RITEMED SILK, KEYSILK, Q-CLOSE SILK, U-SILK, SETA, SEIDE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyamide Suture	TRULON	VETSUTURE NYLON, NOÉCARE NYLON, NOÉDENTAL NYLON, ALAN LON, NYLAMIDE, N-CARE NYLON, RITEMED NYLON, KEYLON, Q-CLOSE NYLON, U-LON, MONOMYD, NYLON	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polypropylene Suture	TRULENE	VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE, ALAN LENE, PROPYL CUT, N-CARE POLYPROPYLENE, RITEMED POLYPROPYLENE, KEYLENE, Q-CLOSE POLYP, U-LENE, MOPYLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyester Suture	TRUBOND	VETSUTURE BOND, NOÉCARE BOND, NOÉDENTAL BOND, ESTERCUT, N-CARE POLYESTER, RITEMED POLYESTER, KEYCRON, Q-CLOSE BOND, ALAN ESTER, U-BOND, POLYTEK	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

Product name: Sterile Partially Absorbable Surgical Mesh

Generic Name	Brand Name	Additional Brand Name(s)	Size (cm)
Polyglycolic Acid/ Polypropylene Mesh	PROSORB MESH	Q-CLOSE DUOMESH	11 x 6, 15 x 7.5, 10 x 15, 15 x 15, 30 x 30



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3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovakia
Notified Body No. 2265

EC DESIGN-EXAMINATION CERTIFICATE

No. 2017-MDD/DE-056/B

issued in compliance with the Council Directive 93/42/EEC as amended 2007/47/EC, which is implemented by the Slovak Government Decree No. 582/2008 Coll. as amended by 215/2013 Coll., certifies that the design of medical device of Class III,

Sterile Absorbable Surgical Suture with or without needle
Sterile Non-absorbable Surgical Suture with or without needle
Sterile Partially Absorbable Surgical Mesh

(for detailed list refer to Annex; pages 1 to 2)

manufactured by company

Healthium Medtech Private Limited
Plot No. 1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post,
Satyavedu Mandal, Chittoor District, Andhra Pradesh - 517 588, India

conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC taking into account intended use of the device.

The Notified Body No. 2265 has performed a design-examination of the device according to Annex II.4 of the Directive 93/42/EEC. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocols No. 310300/2017, 310300A/2018 and 310300B/2019.

This certificate is issued under the following conditions:

It applies only to the design of the above referenced model of the medical device and it does not imply the Notified Body executed any surveillance or control of its manufacture. The manufacturer is obligated to assure that all medical devices of the respective model conform to the type whose design has been approved by this certificate. The certificate remains valid until the approved design is changed but till November 9th, 2022 at the latest. This EC design-examination certificate is complementary to an EC Certificate, approving the manufacturer's quality system according to the Directive 93/42/EEC as amended by 2007/47/EC, Annex II excluding (4).



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ANNEX TO EC DESIGN-EXAMINATION CERTIFICATE No. 2017-MDD/DE-056/B

issued for the company

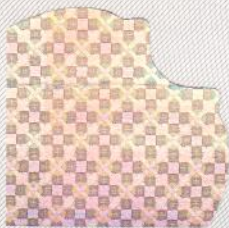
Healthium Medtech Private Limited
Plot No. 1600, R-6 West, Sri City (SEZ), Cherivi Village, Irrugulam Post,
Satyavedu Mandal, Chittoor District, Andhra Pradesh - 517 588, India

List of medical devices covered by the EC Design-Examination Certificate:

Product name: Sterile Absorbable Surgical Suture with or without needle

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Polyglycolic Acid Suture	TRUGLYDE	POGAL, N-CARE PGA, IGLYDE, RITEMED PGA, GEYCOL, ALAN GLYDE, U-GLYDE, PGA RESORBA	9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglycolic Acid Suture (Fast absorbable)	TRUGLYDE FAST	POGAL FAST, N-CARE PGA FAST, RITEMED PGA FAST, GEYCOL FAST, ALAN GLYDE FAST, U-GLYDE FAST, PGA RESOQUICK	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglactin 910 Suture	TRUSYNTH	VETSUTURE PGLA, NOÉCARE PGLA, NOÉDENTAL PGLA, POGAL 910, N-CARE POLYGLACTIN 910, ISYNTH, RITEMED PGLA, GEY910, Q-CLOSE SYNTH, U-SYNTH	9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polyglactin 910 Suture (Fast absorbable)	TRUSYNTH FAST	VETSUTURE FASTPGLA, NOÉCARE FASTPGLA, NOÉDENTAL FASTPGLA, ALANLACT FAST, POGAL 910 FAST, N-CARE POLYGLACTIN 910 FAST, ISYNTH FAST, RITEMED PGLA FAST, Q-CLOSE SYNTH FAST, U-SYNTH FAST, FYSORB	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Polydioxanone Suture	PD SYNTH	VETSUTURE PDX, NOÉCARE PDX, NOÉDENTAL PDX, PDX, N-CARE PD SYNTH, RITEMED POLYDIOXONONE, Q-CLOSE PDSYNTH, ALAN ANONE, PDO RESORBA	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2
Poliglecaprone 25 Suture	MONOGLYDE	VETSUTURE PGC, NOÉCARE PGC, NOÉDENTAL PGC, POGAL MONO, N-CARE MONOGLYDE, RITEMED POLIGLECAPRONE, GEYCRYL, Q-CLOSE MONO, ALAN GLECA, FYSORB MONO	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2

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List of medical devices covered by the EC Design-Examination Certificate:

Product name: Sterile Non-absorbable Surgical Suture with or without needle

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Silk Suture	TRUSILK	VETSUTURE SILK, NOÉCARE SILK, NOÉDENTAL SILK, ALAN SILK, SILKCUT, N-CARE SILK, ISILK, RITEMED SILK, KEYSILK, Q-CLOSE SILK, U-SILK, SETA, SEIDE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyamide Suture	TRULON	VETSUTURE NYLON, NOÉCARE NYLON, NOÉDENTAL NYLON, ALAN LON, NYLAMIDE, N-CARE NYLON, RITEMED NYLON, KEYLON, Q-CLOSE NYLON, U-LON, MONOMYD, NYLON	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polypropylene Suture	TRULENE	VETSUTURE LENE, NOÉCARE LENE, NOÉDENTAL LENE, ALAN LENE, PROPYLCUT, N-CARE POLYPROPYLENE, RITEMED POLYPROPYLENE, KEYLENE, Q-CLOSE POLYP, U-LENE, MOPYLENE	10-0, 9-0, 8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4
Polyester Suture	TRUBOND	VETSUTURE BOND, NOÉCARE BOND, NOÉDENTAL BOND, ESTERCUT, N-CARE POLYESTER, RITEMED POLYESTER, KEYCRON, Q-CLOSE BOND, ALAN ESTER, U-BOND, POLYTEK	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

Product name: Sterile Partially Absorbable Surgical Mesh

Generic Name	Brand Name	Additional Brand Name(s)	Size (cm)
Polyglycolic Acid/ Polypropylene Mesh	PROSORB MESH	Q-CLOSE DUOMESH	11 x 6, 15 x 7.5, 10 x 15, 15 x 15, 30 x 30

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