

Healthium Medtech Limited
No. 472 D, 13th Cross, 4th Phase, Peenya
Industrial Area,
560 058 Bangalore, Karnataka, India

Our reference
LUL/2021/019

Contact person
Ľubor Lysák / +421 2 5831 8343

BRATISLAVA
September 2, 2021

Subject: Confirmation of the announced change

To whom it may concern,

This is to confirm that 3EC International a.s. approves the announced change of trade name as follows:

Previous trade name:

Healthium Medtech Private Limited

No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

New trade name:

Healthium Medtech Limited

No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

Implementation of the change does not represent a significant change in design or intended purpose under Art. 120 sec.3 of the Regulation (EU) 2017/745 on medical devices as amended. The related EC certificates are listed in the Annex and remains valid until the date stated on the certificates. This confirmation corrects / complements the information on the above-mentioned certificate.

Yours sincerely

3EC International a.s.
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

3EC International a.s.

Ľubor Lysák

Deputy Director of NB2265 & In-house Counsel

Annex: List of affected EC certificates

2020-MDD/QS-127
2020-MDD/DE-128
2020-MDD/QS-129
2020-MDD/DE-130
2020-MDD/QS-125
2020-MDD/DE-126
2020-MDD/QS-122
2020-MDD/DE-123
2018-MDD/QS-037/B
2018-MDD/DE-038/B
2018-MDD/QS-039/B
2018-MDD/DE-040/B
2020-MDD/QS-131
2020-MDD/QS-132
2018-MDD/QS-041
2018-MDD/QS-042/B
2020-MDD/QS-012
2020-MDD/QS-124



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

EC DESIGN-EXAMINATION CERTIFICATE

No. 2020-MDD/DE-130

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the design of medical device of Class III,

Sterile Non-absorbable Surgical Suture with or without needle

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

manufactured by company

Healthium Medtech Private Limited
No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

conforms with the relevant provisions of Annex II.4 of the Directive 93/42/EEC as amended on medical devices as transposed into national legislation. The device fulfils the essential requirements specified in Annex I of the Directive 93/42/EEC as amended taking into account intended purpose 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 as amended. The detailed device description, design dossier and evaluation of the examination are presented in the Final protocol No. 310513/2020.

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 May 26th, 2024 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, Annex II (excluding 4).




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

At Bratislava, on December 27th, 2020
This certificate supersedes the EC Design-Examination Certificate No. 2020-MDD/DE-053/B
issued on January 21st, 2019

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	December 27 th , 2020	310513	Recertification



ANNEX TO EC DESIGN-EXAMINATION CERTIFICATE No. 2020-MDD/DE-130

issued for the company

Healthium Medtech Private Limited
No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

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, ALPHA SILK, ADVAMED-SILK, ISILK, RITEMED BLACK BRAIDED SILK, LINX SILK, KEYSILK, SILK, Q-CLOSE SILK, U-SILK, SETA, SEIDE, SURGISUT TRUSILK, TRUVET SILK, IM-SILK, ESILK, UNODENT SILK, TRUDENT SILK	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, ALPHA LON, ADVAMED-NYLON, RITEMED MONOFILAMENT NYLON, LINX NYLON, KEYLON NYLON, NYLON POLYAMIDE, Q-CLOSE NYLON, U-LON, MONOMYD, SURGISUT TRULON, B-LON, HM-LON, TRUVET NYLON, IM-LON, ELYAMIDE, UNODENT NYLON, TRUDENT 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, ALPHA LENE, ADVAMED-POLYPROPYLENE, RITEMED MONOFILAMENT POLYPROPYLENE, LINX PROLINE, KEYLENE POLYPROPYLENE, LENE POLYPROPYLENE, Q-CLOSE POLYP, U-LENE, MOPYLEN, MOPYLEN CV, SURGISUT TRULENE, B-LENE, HM-LENE, TRUVET POLYPROPYLENE, IM-LENE, EPLYENE, UNODENT POLYPROPYLENE, TRUDENT POLYPROPYLENE	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, ALPHABOND, ADVAMED-POLYESTER, RITEMED COATED POLYESTER, KEYCROX POLYESTER, BOND POLYESTER, Q-CLOSE BOND, LINX BOND, U-BOND, POLYTEK, SUPOLENE, SUPOLENE CV, SURGISUT TRUBOND, B-BOND, HM-BOND, TRUVET POLYESTER, IM-BOND, ELYESTER, UNODENT POLYESTER, TRUDENT POLYESTER	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

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At Bratislava, on December 27th, 2020
Valid until May 26th, 2024



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

Healthium Medtech Limited
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Industrial Area,
560 058 Bangalore, Karnataka, India

Our reference
LUL/2021/019

Contact person
Ľubor Lysák / +421 2 5831 8343

BRATISLAVA
September 2, 2021

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This is to confirm that 3EC International a.s. approves the announced change of trade name as follows:

Previous trade name:

Healthium Medtech Private Limited

No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

New trade name:

Healthium Medtech Limited

No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

Implementation of the change does not represent a significant change in design or intended purpose under Art. 120 sec.3 of the Regulation (EU) 2017/745 on medical devices as amended. The related EC certificates are listed in the Annex and remains valid until the date stated on the certificates. This confirmation corrects / complements the information on the above-mentioned certificate.

Yours sincerely

3EC International a.s.
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

3EC International a.s.

Ľubor Lysák

Deputy Director of NB2265 & In-house Counsel

Annex: List of affected EC certificates

2020-MDD/QS-127
2020-MDD/DE-128
2020-MDD/QS-129
2020-MDD/DE-130
2020-MDD/QS-125
2020-MDD/DE-126
2020-MDD/QS-122
2020-MDD/DE-123
2018-MDD/QS-037/B
2018-MDD/DE-038/B
2018-MDD/QS-039/B
2018-MDD/DE-040/B
2020-MDD/QS-131
2020-MDD/QS-132
2018-MDD/QS-041
2018-MDD/QS-042/B
2020-MDD/QS-012
2020-MDD/QS-124



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

EC CERTIFICATE

No. 2020-MDD/QS-129

issued in compliance with the Council Directive 93/42/EEC as amended,
certifies that the medical device of Class III,

Sterile Non-absorbable Surgical Suture with or without needle

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

manufactured by company

Healthium Medtech Private Limited
No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, India

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

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. The detailed description of the system, requirements and measures applied by the manufacturer are presented in the Audit Report No. ICT_122 and the Final protocol No. 310513/2020.

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 May 26th, 2024 at the latest. The certificate validity is conditional upon positive results of regular surveillance audits and fulfillment 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, Annex II (4) is required.



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

At Bratislava, on December 27th, 2020

This certificate supersedes the EC Certificate No. 2017-MDD/QS-052/B issued on January 21st, 2019

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	December 27 th , 2020	310513	Recertification



ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-129

issued for the company

Healthium Medtech Private Limited
No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area,
560 058 Bangalore, Karnataka, 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, ALPHA SILK, ADVAMED-SILK, ISILK, RITEMED BLACK BRAIDED SILK, LINX SILK, KEYSILK, SILK, Q-CLOSE SILK, U-SILK, SETA, SEIDE, SURGISUT TRUSILK, TRUVET SILK, IM-SILK, ESILK, UNODENT SILK, TRUDENT SILK	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, ALPHA LON, ADVAMED-NYLON, RITEMED MONOFILAMENT NYLON, LINX NYLON, KEYLON NYLON, NYLON POLYAMIDE, Q-CLOSE NYLON, U-LON, MONOMYD, SURGISUT TRULON, B-LON, HM-LON, TRUVET NYLON, IM-LON, ELYAMIDE, UNODENT NYLON, TRUDENT 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, ALPHA LENE, ADVAMED-POLYPROPYLENE, RITEMED MONOFILAMENT POLYPROPYLENE, LINX PROLINE, KEYLENE POLYPROPYLENE, LENE POLYPROPYLENE, Q-CLOSE POLYP, U-LENE, MOPYLEN, MOPYLEN CV, SURGISUT TRULENE, B-LENE, HM-LENE, TRUVET POLYPROPYLENE, IM-LENE, EPLYENE, UNODENT POLYPROPYLENE, TRUDENT POLYPROPYLENE	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, ALPHABOND, ADVAMED-POLYESTER, RITEMED COATED POLYESTER, KEYCRON POLYESTER, BOND POLYESTER, Q-CLOSE BOND, LINX BOND, U-BOND, POLYTEK, SUPOLENE, SUPOLENE CV, SURGISUT TRUBOND, B-BOND, HM-BOND, TRUVET POLYESTER, IM-BOND, ELYESTER, UNODENT POLYESTER, TRUDENT POLYESTER	8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2, 3, 4, 5

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At Bratislava, on December 27th, 2020
Valid until May 26th, 2024



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