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

Our reference	***Contact person***	BRATISLAVA
LUL/2021/019	Ľubor Lysák / +421 2 5831 8343	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-123

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

Sterile Polydioxanone Knotless Tissue – Closure Device

(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. 310516/2020.

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).

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

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

At Bratislava, on December 27th, 2020

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	December 27th, 2020	310516	First issue of the Certificate

ANNEX TO EC DESIGN-EXAMINATION CERTIFICATE
No. 2020-MDD/DE-123

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 Polydioxanone Knotless Tissue – Closure Device

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Sterile Polydioxanone Knotless Tissue – Closure Device	TRUBARB	TRUQUICK, TRULOCK, PDX BARBED, LINX BARBED, IM-BARBED, RESORBA BARBED SUTURE, Q-CLOSE BARBED SUTURE	5-0, 4-0, 3-0, 2-0, 0, 1

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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

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

Our reference	***Contact person***	BRATISLAVA
LUL/2021/019	Ľubor Lysák / +421 2 5831 8343	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

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

EC CERTIFICATE

No. 2020-MDD/QS-122

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

Sterile Polydioxanone Knotless Tissue – Closure Device

(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. 310516/2020.

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.

Notified body
3EC International
NB 2265
NOTIFIKOVANÁ OSOBA

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

At Bratislava, on December 27th, 2020

Certificate history:

Revision	Date of issue	Application for Conformity Assessment of MD number	Description
0	December 27th, 2020	310516	First issue of the Certificate

ANNEX TO EC CERTIFICATE No. 2020-MDD/QS-122

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 Polydioxanone Knotless Tissue – Closure Device

Generic Name	Brand Name	Additional Brand Name(s)	USP Size
Sterile Polydioxanone Knotless Tissue – Closure Device	TRUBARB	TRUQUICK, TRULOCK, PDX BARBED, LINX BARBED, IM-BARBED, RESORBA BARBED SUTURE, Q-CLOSE BARBED SUTURE	5-0, 4-0, 3-0, 2-0, 0, 1

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

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

3EC®
international

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

Attn. Dr. Ashok Moharana, Chief Medical Officer

Our reference	***Contact person***	BRATISLAVA
NAA/2023/P012	Natália Achimská / +421 2 5831 8343	29.9.2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number (if available): IN-MF-000008421

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

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

Katarína Tomin Srdošová, PhD.
Director of NB2265

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Bone Wax (Trade Name: TRUWAX, Q-Close Bone Wax, LINX-WAX, BONEWAX BW25, SURGISUT TRUWAX, IM WAX, DTEK BONEWAX)	Class IIb excluding Class IIb implantable non-WET	N/A	2018-MDD/QS-037/B, NB2265 2018-MDD/DE-038/B, NB2265
ABSORBABLE HEMOSTAT OXIDIZED REGENERATED CELLULOSE (Trade Name: Clinicel, Q-Close Cel, Q-Close Stat, LINXCEL, SURGISUT CLINICEL)	Class III	N/A	2018-MDD/QS-039/B, NB2265 2018-MDD/DE-040/B, NB2265
STERILE POLYDIOXANONE KNOTLESS TISSUE-CLOSURE DEVICE (Trade Name: TRUBARB, TRUQUICK, TRULOCK, PDX BARBED, LINX BARBED, IM-BARBED, RESORBA BARBED	Class III	N/A	2020-MDD/QS-122, NB2265 2020-MDD/DE-123, NB2265

SUTURE, Q-CLOSE BARBED SUTURE)			
STERILE SURGICAL SUTURE NEEDLE - SPRING EYE (Trade Name: FEDEROHRNADELN)	Class IIa	N/A	2020-MDD/QS-124, NB2265
Sterile Skin Stapler (Trade Name: TruPler, Dermator, Q Close Skin Stapler, Trupler Neo, Trupler Eco, Surgipler, Healier, LINX Stapler, SURGISUT TRUPLER)	Class IIa	N/A	2018-MDD/QS-042/B, NB2265
Sterile Skin Staples Remover (Trade Name: X-Tract, Q close X-tract)	Class I devices placed on the market in sterile condition	N/A	2020-MDD/QS-012, NB2265
Sterile Umbilical Cotton Tape (Trade Name: Umbilical Cotton Tape, Q-Close Umbilical Cotton Tape)	Class I devices placed on the market in sterile condition	N/A	2018-MDD/QS-041, NB2265

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/09/29	NAA/2023/P012	Initial issue