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international

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

EC CERTIFICATE

No. 2018-MDD/QS-037/A

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 Bone Wax
Brand name: TRUWAX, Q-Close Bone Wax, LINX-WAX, BONEWAX BW25

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 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. 02-0131-18 & 02-0131-19 and the Final protocol No. 310322/2018 & 310322A/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 December 14th, 2023 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.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

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

In Bratislava, on February 6th, 2020
Version A) supersedes the EC Certificate No. 2018-MDD/QS-037 issued on December 15th, 2018

Digitally signed by Ceaicovschi Tudor
Date: 2022.10.27 10:20:39 EEST
Reason: MoldSign Signature
Location: Moldova

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

EC DESIGN-EXAMINATION CERTIFICATE

No. 2018-MDD/DE-038/A

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 Bone Wax

Brand name: TRUWAX, Q-Close Bone Wax, LINX-WAX, BONEWAX BW25

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 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 protocol No. 310322/2018 & 310322A/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 December 14th, 2023 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).

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

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

In Bratislava, on February 6th, 2020
Version A) supersedes the EC Design-Examination Certificate No. 2018-MDD/QS-038 issued on December 15th, 2018

EC DECLARATION OF CONFORMITY	
Product Group	Bonewax
GMDN Code	46930
Brand Name	**Truwax**
Generic Name	Sterile bonewax
Indented Use: Truwax may be used for the control of bleeding from bone surfaces.	
Quality Responsibility: Healthium Medtech Pvt Ltd., Bangalore declares under Sole responsibility for complying all The quality requirements of the product.	
Address (office and Factory) of the Manufacturer:	No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, Bangalore – 560 058, India Ph: +91-80-41868000 Fax: +91-80-41171056
E.U. Representative's name and address	MED DEVICES LIFESCIENCES B.V. Kraijenhoffstraat 137 A, 1018RG Amsterdam, Netherlands Email: info@meddevices.net Phone: +31-202254558
Classification of the device:	Truwax is classified as **Class III device** in accordance with Rule 8 of Annex IX of the MDD 93/42/EEC.
Conformity Assessment Route	Annexure ll, excluding (4) (Module H) of MDD 93/42/EEC Council directives as amended by 2007/47/EC
Notified Body's Address and **Notified body number**	**3EC International a.s. Hranicna 18, 821 05 Bratislava, Slovak Republic.** **NB 2265**
Certificate No.:	**2018-MDD/QS-037/A**
Document Reference No.	**TF/CE/04**
Applicable Standards	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1 : 2016 , EN 1041:2008, EN 556-1: 2001, EN 556-2: 2015, ISO 11135: 2014, ISO 10993-1:2009, ISO 10993-5: 2009, EN ISO-10993-6 :2009, ISO 10993-7: 2008, ISO 10993-10: 2010, ISO 10993-13: 2010, EN ISO-10993-11 : 2009, EN ISO-11607-1 : 2009, EN ISO-11607-2 : 2006, EN ISO-11737-1: 2006, EN ISO 11737-2: 2009, EN ISO-14630 : 2012, ISO 14644-1:2015, EN 868-7:2017, MEDDEV 2.7-1 rev 4, MEDDEV 2.12-1 rev 8, MEDDEV 2.12-2 rev 2
Declaration: Healthium Medtech Pvt. Ltd declares that Truwax meets the requirements of Quality as per the in-house specifications, and also complies with the provisions of the council of Directives 93/42/EEC as amended by 2007/47/EC Directives for Medical devices.	
Signature :	
Name and Position	**Malesh. M** Regulatory Affairs
Date	**27.03.2020**
Place	**Bangalore**

USNAS
Reg. No. 305/Q-050

CERTIFICATE

This certifies that the Quality management system *of company*

Healthium Medtech Limited

No. 472 D, 13th Cross, 4th Phase, Péenyç1 Industriai Area, 560 058 Bangalore, Karnataka, India
Site 1: #472-D 1'3TH éROSS, 4TH PHASE, PEENYA INDUSTRIALAREA, BANGALQRE, KI\RNATAKA-560058, INDIA

has *been assessed by 3EC International*
and found to be in col)forntance with the following standard:

ISO 9001:2015

tor the fòllowing scope:·

DESIGN, MANUFACTURE ANO. SALtS OF NQN•ACTIVE .STERILE MEDICAL DEVICES, DEVICES- FOR WOIJND CARE; .ABSORBABLE AND,NQN ABSORBABLE SURGICAL SUTURES AT;rACHEÒ WITH ATRAUMATIe NEEOLE OR WJtHOUT NEEDLE, ABSORBABLE HEMOSTAT, J"EMPORARY CARDIAC PACING WIRES, SURGICAL MESHES,· BONE ,WAX, STERILE SKI STAPLER, SKIN STAPLES REMOVER, ENDO STAPLERS, KNOTLESS TISSUE CLOSURE DEVICES, LIGATING CLIPS, SURGICAL NEEDLE -SPRING EYE AND UMBILICAL COTTON TAPE

Certificate No.: Q--0868A/21 **Date of issuance: August 6th, 2021** **Originai c;late of approva1: July 22.nd, 202-1**

This certificate is valid from August 6th, 2021 to July 21st, 2024 on conditic;m that organization will maintain effectivé' Quality management system. To verify the validity of this certifiéate please contact our, officé at; +421 (0)2 5831 8343.

Thls certificate ful/y super.sedes previous certifícate No. Q-0868121 **issliecion** *.July 22nd;* **202t.**

Issuing office: 3EC InternationaJ **a.s.**, *Hranicna 18, 821 05 Bratislava, Slovak Repùblic*

Dr. Katarina Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certificatron body 3ÈC Internat/onal a.s, is accredited by SNAS under registration number 305/Q-050 With accreditation certificate No. Q-050 lor certification of Quarrty management systems covered by EA MLA and IAF MLA.

3EC International

SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

Healthium Medtech Limited

No. 472 D, 13th Cross, 4th Phase, Peenya Industrial Area, 560 058 Bangalore, Karnataka, India
Site 1: #472-D, 13TH CROSS, 4TH PHASE, PEENYA INDUSTRIAL AREA, BANGALORE, KARNATAKA-560058, INDIA

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN, MANUFACTURE AND SALES OF NON-ACTIVE STERILE MEDICAL DEVICES, DEVICES FOR WOUND CARE; ABSORBABLE AND NON ABSORBABLE SURGICAL SUTURES ATTACHED WITH ATRAUMATIC NEEDLE OR WITHOUT NEEDLE, ABSORBABLE HEMOSTAT, TEMPORARY CARDIAC PACING WIRES, SURGICAL MESHES, BONE WAX, STERILE SKIN STAPLER, SKIN STAPLES REMOVER, ENDO STAPLERS, KNOTLESS TISSUE CLOSURE DEVICES, LIGATING CLIPS, SURGICAL NEEDLE -SPRING EYE AND UMBILICAL COTTON TAPE

Certificate No.: M-0510A/21 **Date of issuance: August 6th, 2021** **Original date of approval: July 22nd, 2021**

This certificate is valid from **August 6th, 2021** to **July 21st, 2024** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

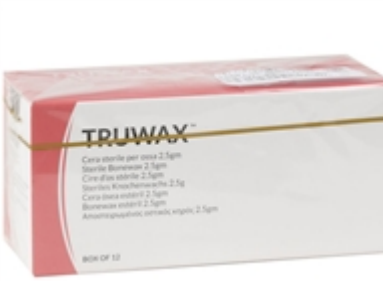
This certificate fully supersedes previous certificate No. M-0510/21 issued on July 22nd, 2021.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices.

TRUWAX SURGICAL BONEWAX 2.5 g - sterile



Code:	**23000**
Category:	**Sutures**
Unit of sale:	**box of 12 pcs.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**III**
NSIS:	**1920416**
CND:	**M040599**
EAN13:	**8023279230000**

Description:

TRUWAX STERILE SURGICAL BONEWAX 2.5 g
Equivalent Ethicon brand: BONE WAX

Truwax is a sterile mixture of beeswax, paraffin wax and iso propyl palmitate (bone wax). It can be safely used to control bleeding from surfaces of injured bones during bone repair surgery.

Multilanguage manual and box: GB, FR, IT, ES, PT, DE, GR.

Technical Specifications:

Composition: Bees wax I.P., White Hard Paraffin Wax, I.P., Iso Propyl Palmitate, U.S.P.
Colour - Odour: opaque - waxy odour
Sterilization: gamma radiation
Shelf life: 5 years
Packing: 2.5 g per unit pack