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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

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).

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