



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

EC CERTIFICATE

No. 2017-MDD/QS-051/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 IIb,

Sterile Non-absorbable Surgical Suture with or without needle

Sterile Non-absorbable Surgical Mesh

(for detailed list refer to Annex)

manufactured by company

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

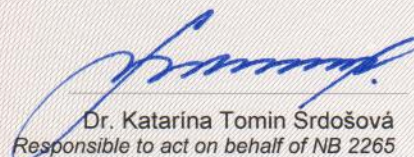
is manufactured under conditions fulfilling the quality system requirements of Annex II, excluding (4), of the Directive 93/42/EEC as amended by 2007/47/EC.

The Notified Body No. 2265 has performed an audit of the above device quality system. The full quality assurance system has been assessed and found that it meets the requirements above. The quality system 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. 310299, and the Final protocols No. 310299/2017 and 310299A/2018.

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of the above referenced model of medical device 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.




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

In Bratislava, on February 15th, 2018

Version A) supersedes the EC Certificate No. 2017-MDD/QS-051 issued on November 10th, 2017



ANNEX TO EC CERTIFICATE No. 2017-MDD/QS-051/A

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
Monofilament Stainless Steel LVM 316 Grade wire	TRUSTEEL	ALPHA STEEL, ADVAMED-STEEL SUTURE, Q-CLOSE STEEL	1, 2, 3, 4, 5, 6, 7

Product name: Sterile Non-absorbable Surgical Mesh

Generic Name	Brand Name	Additional Brand Name(s)	Size (cm)
Polypropylene Mesh	TRULENE MESH	ALPHA LENE MESH, LINX REGULAR MESH, LINX LIGHT MESH, Q-CLOSE MESH, ADVAMED – POLYPROPYLENE MESH	2.5 x 10, 3 x 6, 4 x 6, 4 x 9, 5 x 7.5, 6 x 5, 6.5 x 13.5, 5 x 9, 5 x 10, 6 x 11, 6 x 6, 7.5 x 15.2, 7.6 x 10, 7.2 x 11.7, 7.6 x 10, 7.6 x 15, 7 x 11, 7.5 x 7.5, 7.5 x 12.5, 8.5 x 11, 8 x 13, 8 x 15, 8 x 10, 8 x 12, 8 x 11, 8 x 15, 8.5 x 13, 10 x 15, 10 x 12, 10.5 x 10.5, 10 x 10, 10.5 x 11.5, 10 x 13, 10 x 15, 10 x 14, 10 x 25, 12.5 x 15, 12 x 18, 12 x 8, 12 x 12, 13.5 x 13.5, 13.7 x 6, 15 x 15, 15 x 20, 15 x 30, 15 x 19, 20 x 10, 20 x 15, 20 x 20, 20 x 25, 20 x 30, 26 x 30, 27 x 27, 30 x 30, 30 x 20

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In Bratislava, on February 15th, 2018
Valid until November 9th, 2022

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