By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 570496**

Issued To: **Novus Scientific AB**
Virdings Allé 2
Uppsala
SE-75450
Sweden

In respect of:

TIGR® Matrix Surgical Mesh

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **02 August 2011** Date: **28 July 2016** Expiry Date: **01 August 2021**

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Supplementary Information to CE 570496

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Product Code	Description
NSTM1015E	TIGR® Matrix Surgical Mesh, 10 x 15cm
NSTM1520E	TIGR® Matrix Surgical Mesh, 15 x 20cm
NSTM2030E	TIGR® Matrix Surgical Mesh, 20 x 30cm

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Certificate History

Date	Reference Number	Action
02 August 2011	10121080	First issue.
14 September 2012	10133960	Addition of new product code (NSTM2030) and update of IFU (indications & warnings).
23 October 2012	10137573	Administrative update to the product codes.
27 February 2013	10140576	Change of legal manufacturer from Novus Scientific Pte Ltd, Singapore to Novus Scientific AB, Sweden.
08 December 2014	10144963	- Qualification of in-house manufacture. - Approval of NSTM1520E variant. - Qualification of Synergy Health AST, Venlo for ETO Sterilization. - Extension of Shelf-life.
28 July 2016	10163840	Certificate renewal; Updates to contraindications and warnings section of IFU.

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