

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 746093 R000

Manufacturer: Novus Scientific AB

Address:

Virdings Allé 2
Uppsala
SE-75450
Sweden

Single Registration Number: SE-MF-000012938

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-12-23**

Date: **2021-12-23**

Expiry Date: **2026-12-22**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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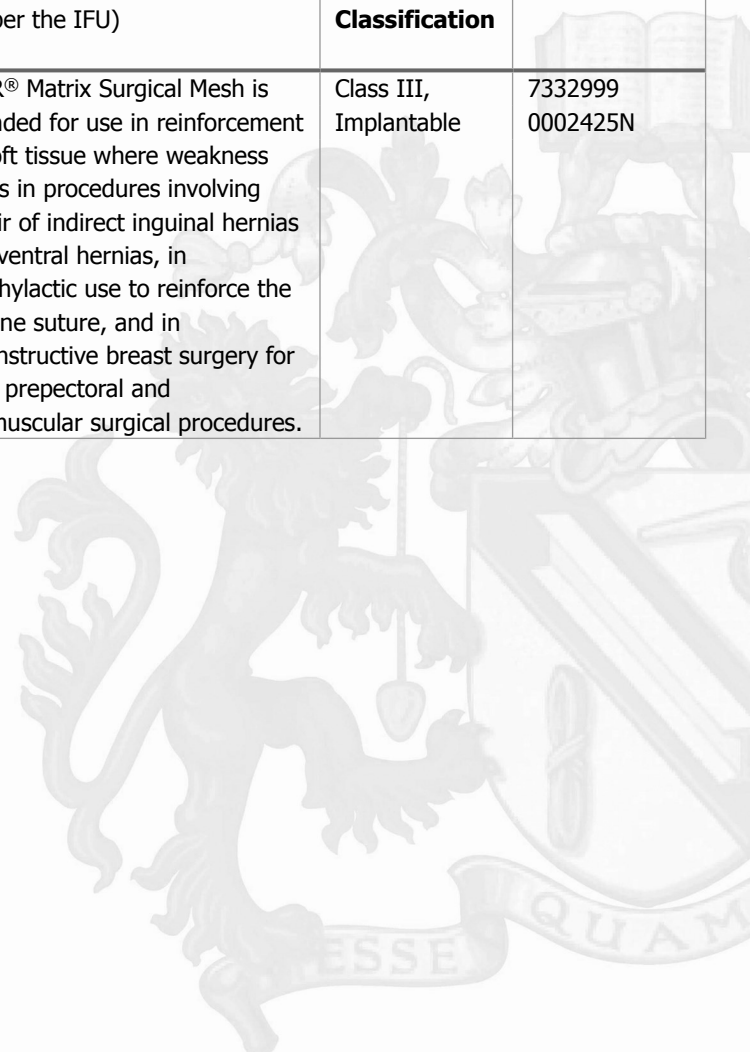
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Device Schedule:

Device Name	Catalogue Number	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Risk Classification	Basic UDI-DI
TIGR® Matrix Surgical Mesh	NSTM1015E	10 x 15cm	MDN 1104 Non-active soft tissue and other implants	TIGR® Matrix Surgical Mesh is intended for use in reinforcement of soft tissue where weakness exists in procedures involving repair of indirect inguinal hernias and ventral hernias, in prophylactic use to reinforce the midline suture, and in reconstructive breast surgery for both prepectoral and submuscular surgical procedures.	Class III, Implantable	7332999 0002425N
	NSTM1520E	15 x 20cm				
	NSTM2030E	20 x 30cm				



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
23 December 2021	3497268	Issued



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