NOVUS SCIENTIFIC

EU Declaration of Conformity

Manufacturer	Novus Scientific AB Virdings Allé 2 SE-754 50 Uppsala, Sweden
Single Registration Number (SRN)	SE-MF-000012938
Person Responsible for Regulatory Compliance (PRRC)	Pär Neidenström, Senior consultant from Key2Compliance AB
PRRC contact details	Adress: Skeppsbron 44, SE-111 30 Stockholm, Sweden Telephone: +46 730241726 Mail: par.neidenstrom@key2compliance.com

Medical device name	TIGR® Matrix Surgical Mesh		
Intended Purpose	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.		
Basic UDI	73 32999 000242 5N		
Article number	NSTM1015E	NSTM1520E	NSTM2030E
Device variants	10 x 15 cm	15 x 20 cm	20 x 30 cm
UDI-DI	73 32999 00003 1	73 32999 00010 9	73 32999 00004 8
Risk class (according to Annex VIII)	Class III, according to rule 8		
GMDN Code	44688		
GMDN Term	Polymer Surgical Mesh, biodegradable		

Notified Body	BSI Group The Netherlands B.V.
Notified Body number	2797
Notified Body address	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Conformity assessment procedure	Annex IX
Certificate ID	MDR 746093

This declaration of conformity is issued under the sole responsibility of Novus Scientific AB. Novus Scientific AB hereby declare that the above mentioned medical devices comply with the applicable parts of the Medical Device Regulation, Regulation (EU) 2017/745.

The design conforms to the requirement of the above regulation and is manufactured under a Quality Management System that complies with the requirements of ISO 13485:2016.

27 Dec 2021

Uppsala, Date

Henrik Magnusson Hjorth, CEO
Signed on behalf of Novus Scientific AB

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