

Certificate

Certificate No.: MD 1554225-1-2

Manufacturer: **GRENA Ltd.**
1000 Great West Road
Brentford, Middlesex
TW8 9HH
United Kingdom

REPs Facility ID: F001093

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68,
PMD Act (as applicable)

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D, 21 CFR 821

Scope: Design and development, manufacture and distribution of sterile and
non-sterile medical devices. Servicing of reusable instruments.

See the next page for products scope

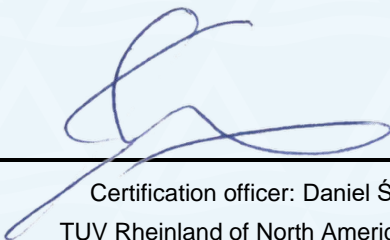
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 84973025-30

Issue Date: 2024-04-25

Effective Date: 2024-05-15

Expiry Date: 2027-05-14



Certification officer: Daniel Świątko
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

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Products scope:

Sterile Ligating Clips made of Titanium, Sterile Ligating Clips made of Polymer, Sterile Disposable Wound Protectors / Retractors, Non-sterile Reusable Clip Appliers for Ligating Clips made of Titanium, Non-sterile Reusable Clip Appliers for Ligating Clips made of Polymer, Non-sterile Reusable Clip Removers for Ligating Clips made of Polymer, Non-sterile Reusable Articulating Clip Appliers for Ligating Clips made of Titanium, Non-sterile Reusable Articulating Clip Appliers for Ligating Clips made of Polymer.

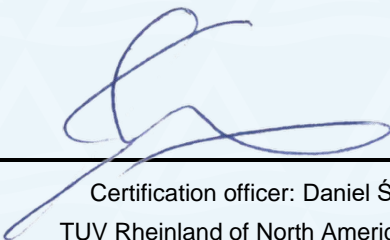
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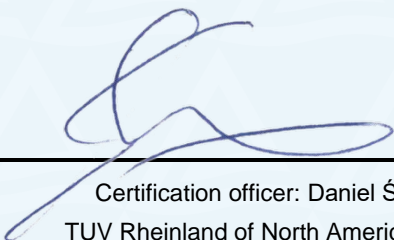
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The scope of certification includes the following additional sites:

No.	Location	Scope
/01	GRENA Ltd. 1000 Great West Road Brentford, Middlesex TW8 9HH United Kingdom	Administration. REPs Facility ID: F001093
/02	GRENA Ltd. Chelsea Street, Chelsea House Nottingham NG7 7HP United Kingdom	Activities associated with design and development, manufacture, distribution, servicing and administration. REPs Facility ID: F005562

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