

EC Certificate



Full Quality Assurance System Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1554225-1

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

Products:

- Ligating clips
- Ligating clip cartridge to be used with reusable automatic clip appliers
- Disposable endoscopic instruments
- Reusable endoscopic instruments
- Disposable Jumbo Pack
- Disposable circular staplers with related surgical instruments
- Disposable linear staplers with cartridges
- Disposable linear cutting staplers with cartridges
- Staples cartridges for reusable linear cutting staplers

Replaces EC Certificate, Registration No.: HD 60147050 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 84953323-70
Effective date: 2021-05-25
Expiry date: 2024-05-26
Issue date: 2021-05-25



Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following additional sites:

No.	Location	Product groups manufactured
/01	GRENA Ltd. 1000 Great West Road Brentford, MIDDLESEX TW8 9HH United Kingdom	Activity: Administration.
/02	GRENA Ltd. Chelsea Street, Chelsea House Nottingham NG7 7HP United Kingdom	Activity: Design, development and manufacture.

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