

EC Certificate

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

Registration No.: HD 60147050 0001

Report No.: 26300270 016

Manufacturer: Grena Ltd.

1000 Great West Road Brentford, Middlesex

TW8 9HH

United Kingdom

Products: (see attachments for products and site included)

Replaces approval, registration no.: HD 60100981 0001

Expiry Date: 2026-05-20

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.

Effective Date: 2022-02-20

Date: 2022-02-20

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Notified Body

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

Attachment to Certificate

Registration No.: HD 60147050 0001 Report No.: 26300270 016

Manufacturer: Grena Ltd.

1000 Great West Road Brentford, Middlesex

TW8 9HH United Kingdom

Products included)

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

Date: 2022-02-20

Notified Body

Sebastian Mniszek



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate

Registration No.: HD 60147050 0001 Report No.: 26300270 016

Manufacturer: Grena Ltd.

1000 Great West Road Brentford, Middlesex

TW8 9HH United Kingdom

Site included:

Grena Limited Chelsea House, Chelsea Street Nottingham, NG7 7HP United Kingdom

Activity: Desing, development and manufacture

Notified Body

Sebastian Mniszek

Date: 2022-02-20