



VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH, UK

Phone +44 131 208 207 6 Fax +44 131 777 80 77

DECLARATION OF CONFORMITY

Manufacturer

Grena Limited
1000 Great West Road
Brentford, Middlesex, TW8 9HH
United Kingdom

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'aV® – Polymer ligating clips (class IIb, rule 8)
Disposable endoscopic surgical instruments (class IIb, rule 9)
Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 7)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staplers removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 7)
Arida® absorbing pads (class I, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)

Classification

According to Annex IX of Directive 93/42/EEC

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Notified Body



TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60100981 0001
DD 60100980 0001

Brentford, 05.05.2015

Wiesław Brodaczewski
Director

