

AEON™ Endoscopic Stapler

Declaration of Conformity

AEON™ Endoscopic Stapler

3.1. Legal Manufacturer

Lexington Medical, Inc.

23 Crosby Drive, Bedford, Massachusetts 01730 USA

3.2. Authorized Representative

Advena Ltd.

Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

3.3. This Declaration of Conformity is Issued Under Sole Responsibility of Lexington Medical, Inc.

3.4. Product

3.4.1. Product Category

Sterile, Endo-mechanical and Abdominal Surgical Instruments

3.4.2. Product Name

AEON™ Endoscopic Stapler

3.4.3. Model Descriptions:

Endoscopic Stapler Handles:

PRODUCT CODE	PRODUCT DESCRIPTION	DATE OF FIRST CE MARKING
AESH160	AEON™ Endoscopic Stapler Handle Medium	2018-10-01
AESH260	AEON™ Endoscopic Stapler Handle Long	2018-10-01
AESH060	AEON™ Endoscopic Stapler Handle Short	2021-02-12

Endoscopic Stapler Reloads:

PRODUCT CODE	PRODUCT DESCRIPTION	DATE OF FIRST CE MARKING
AESR45G	AEON™ Endoscopic Stapler 2.0mm/45mm Reload	2018-10-01
AESC45G	AEON™ Endoscopic Stapler Curved 2.0mm/45mm Reload	2019-06-24
AESR45T	AEON™ Endoscopic Stapler 2.5mm/45mm Reload	2018-10-01
AESR45W	AEON™ Endoscopic Stapler 2.5mm/45mm Reload	2018-10-01
AESC45T	AEON™ Endoscopic Stapler Curved 2.5mm/45mm Reload	2019-06-24
AESC45W	AEON™ Endoscopic Stapler Curved 2.5mm/45mm Reload	2019-06-24
AESR60T	AEON™ Endoscopic Stapler 2.5mm/60mm Reload	2018-10-01
AESR60W	AEON™ Endoscopic Stapler 2.5mm/60mm Reload	2018-10-01
AESR45R	AEON™ Endoscopic Stapler 3.25mm/45mm Reload	2018-10-01
AESC45R	AEON™ Endoscopic Stapler Curved 3.25mm/45mm Reload	2019-08-29

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AESR60R	AEON™ Endoscopic Stapler 3.25mm/60mm Reload	2018-10-01
AESR45P	AEON™ Endoscopic Stapler 4.0mm/45mm Reload	2018-10-01
AESC45P	AEON™ Endoscopic Stapler Curved 4.0mm/45mm Reload	2019-08-29
AESR60P	AEON™ Endoscopic Stapler 4.0mm/60mm Reload	2018-10-01
AESR60B	AEON™ Endoscopic Stapler 5.0mm/60mm Reload	2018-10-01
AESC60W	AEON™ Endoscopic Stapler Curved 2.5mm/60mm Reload	2021-03-19
AESC60R	AEON™ Endoscopic Stapler Curved 3.25mm/60mm Reload	2021-03-19
AESC60P	AEON™ Endoscopic Stapler Curved 4.0mm/60mm Reload	2021-03-19
ASR60WS	AEON™ Endoscopic Stapler Short 2.5mm/60mm Reload	2021-04-20
ASR60RS	AEON™ Endoscopic Stapler Short 3.25mm/60mm Reload	2021-04-20
ASR60PS	AEON™ Endoscopic Stapler Short 4.0mm/60mm Reload	2021-04-20
AESR30W	AEON™ Endoscopic Stapler 2.5mm/30mm Reload	2021-07-16
ASR30WC	AEON™ Endoscopic Stapler Curved 2.5mm/30mm Reload	2021-07-16
ASR30WS	AEON™ Endoscopic Stapler Short 2.5mm/30mm Reload	2021-09-24
AESR30G	AEON™ Endoscopic Stapler 2.0mm/30mm Reload	2021-12-27
ASR30GC	AEON™ Endoscopic Stapler Curved 2.0mm/30mm Reload	2021-12-27
ASR30GS	AEON™ Endoscopic Stapler Short 2.0mm/30mm Reload	2021-12-27
AESR30R	AEON™ Endoscopic Stapler 3.25mm/30mm Reload	2021-12-27
ASR30RC	AEON™ Endoscopic Stapler Curved 3.25mm/30mm Reload	2021-12-27
ASR30RS	AEON™ Endoscopic Stapler Short 3.25mm/30mm Reload	2021-12-27
AESR30P	AEON™ Endoscopic Stapler 4.0mm/30mm Reload	2022-02-18
ASR30PC	AEON™ Endoscopic Stapler Curved 4.0mm/30mm Reload	2022-02-18
ASR30PS	AEON™ Endoscopic Stapler Short 4.0mm/30mm Reload	2022-02-18

3.5. GMDN Code

Endoscopic manual linear cutting stapler, single-use	59871
Surgical staple loading unit, cutting (Reloads)	64256

3.6. UMDNS Code

Staples, Tissues	15964
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3.7. NBOG Code

Suture Materials and Clamps	MD 0302
Medical Devices in Sterile Condition	MDS 7006

3.8. Product Classification

Stapler Handle Class IIa as per Rule 6 in Annex IX
 Reload Class IIb as per Rule 8 in Annex IX

3.9. Assessment Route

93/42/EEC, Annex II (Exclusion Section 4)

AEON™ Endoscopic Stapler

We hereby declare that the above-mentioned devices are in conformity with the essential requirements and provisions of European Medical Devices Directive 93/42/ECC as modified by 2007/47/EC.

3.10. Notified Body 0123

TÜV SÜD Product Service GmbH Zertifizierstellen
Ridlerstraße 65
80339 MÜNCHEN, Germany

3.11. CE Certificate

G1 003029 0001 Rev. 00 Expiration 2023-09-30

3.12. International Standards Applied

ISO 10993-1, ISO 11335, ISO 11607-1, -2, ISO 14155, ISO 14630, ISO 14971,
ISO 15223, IEC 62366-1, ASTM F2052, ASTM F2213, ASTM F2119, ASTM F2182

For and on behalf of the company:



Name: Rainer Maas

Title: Director of QA/RA

Place of Issue: Bedford, MA, USA

Date of Issue: February 18, 2022