

Design Dossier: DD-P005
DoC Number/Revision: SCN076646 / Rev A
Product Family: Mechanical
Product Group: Open Linear Stapler

Declaration of Conformity (DoC)

Manufacturer: Name: Ethicon Endo-Surgery, LLC
Address: 475 Calle C
Guaynabo, Puerto Rico 00969 USA

Authorized Representative:

Name: Ethicon Endo-Surgery (Europe) GmbH
Address: Hummelsbuetteler Steindamm 71
22851 Norderstedt
Germany

Products/Model No:

The following PROXIMATE Reloadable Linear Staplers product codes are CE marked:

XR30B, XR30G, XR30V, XR60G, TX30B, TX30G, TX30V, TX60B, TX60G, XR60B

(MDD applicable only)

Directive 93/42/EEC declaration (MDD):

We, Ethicon Endo-Surgery, being the manufacturer, declare that the products listed above meet the applicable provisions of the Medical Device Directive 93/42/EEC including applicable harmonized standards listed in the above referenced Technical File.

Products are classified as Class III, Rule Number 8, per Annex IX.

In order to affix CE marking under this directive, Ethicon Endo-Surgery, has followed the procedure relating to the EC declaration of conformity set out in MDD Annex II excluding (4) and Annex II (4). The full quality system has been certified by TÜV SÜD Product Service GmbH, a Notified Body authorized to carry out such assessments and having the designation 0123 (G1 057666 0061 Rev.00, G7 057666 0056 Rev.01).

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Approved by:

Nathan Anderson
Sr. Director, Quality Make
Ethicon Endo-Surgery, LLC



(Signature)

21 JUL 2020

(Date)