

Number: SCN013282  
Version: V.3  
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## Name: Declaration of Conformity

Windchill Signature History Report			
Signature	Role	Event Date	Vote
Anderson, Nathan [JANPR] (NAnders1)	Quality Engineering	05-May-2021 14:06:52 EDT	Approve
Halsey, Gail [ETHUS] (GHalsey)	Research and Development	06-May-2021 07:38:11 EDT	Approve

**Technical File: TF-N000001**  
**DoC Number/Revision: SCN013282/ Rev\*\*V**  
**Product Family: ENERGY**  
**Product Group: HARMONIC**

## Declaration of Conformity (DoC)

### Manufacturer:

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

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### Authorized Representative:

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

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### Products/Model No:

The following HARMONIC product codes are CE marked:

\*\*HARHPBL, \*\*HARHPBLCN, \*\*HARHPGR, \*\*HARHPGRCN, HDH05, HP054, HP054CN, HPBLUE,  
HPBLUECN, SNGCB, SNGHK, SNGHK2

\*\*Both MDD and RoHS applicable

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### 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 IIb, Rule 9, 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 Annex II excluding (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).

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### Directive 2011/65/EU declaration (RoHS):

We, Ethicon Endo-Surgery, being the manufacturer, declare that the products listed above meet the applicable provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment including applicable harmonized standards listed in the above referenced Technical File.

In order to affix CE marking under 2011/65/EU, Ethicon Endo-Surgery has followed the procedure per Article 7.

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

### Approved by:

Nathan Anderson  
Senior Director, Quality Make  
Ethicon Endo-Surgery, LLC

See Signature in Windchill  
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(Signature)

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(Date)