Number: SCN020209
Version: W.2
Released: 05-May-2021

Name: Declaration of Conformity: Harmonic Ultrasonic Surgical Devices & Enseal Electrosurgical Devices

Windchill Signature History Report			
Signature	**Role**	**Event Date**	**Vote**
Anderson, Nathan [JANPR] (NAnders1)	Quality Engineering	05-May-2021 07:58:00 EDT	Approve
Halsey, Gail [ETHUS] (GHalsey)	Research and Development	04-May-2021 08:10:45 EDT	Approve

Technical File: TF-N000022
DoC Number/Revision: SCN020209, REV **W
Product Family: ENERGY
Product Group: Electrosurgical & Ultrasonic Surgical

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 HARMONIC ultrasonic surgical devices and ENSEAL electrosurgical devices are CE marked:

GEN11, GEN11CN, **HAR1120, **HAR1136, HAR23, HAR36, HAR9F, HAR17F, HARH23, HARH36, HARH45, HARHD20, HARHD36, NSLX120L, NSLG2C14, NSLG2C25, NSLG2C35, NSLG2C45, NSLG2S14, NSLG2S25, NSLG2S35, NSLG2S45, NSLG2C35A, NSLG2C45A, NSLG2S35A, NSLG2S45A

** Both MDD and RoHS applicable

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).

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.

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

See non-electornic signature in **WindChill
(Signature) (Date)