



## DECLARATION OF CONFORMITY

Manufacturer's Name: ETHICON, LLC

Manufacturer's Address: Highway 183 Km 8.3  
San Lorenzo 00754  
Puerto Rico, USA

Authorized Representative: Johnson & Johnson Medical GmbH  
Robert-Koch-Strasse 1  
Norderstedt  
22851  
Germany

Product: DERMABOND™ Topical Skin Adhesive

Product Code(s)/ Product Range and Description: See Attachment 1

Classification: Class IIa (Annex IX, Rule 4)

GMDN Code: 34164

MDD TF Number: ADAPTIV No.100142393

### EC Class IIa Device Declaration

We, Ethicon LLC, hereby declare the above listed Medical Device complies with Council Directive 93/42/EEC as amended by 2007/47/EC. This declaration of conformity is issued under the sole responsibility of the manufacturer.

This declaration is made on the basis of:  
EC Quality System Certificate No CE 549311, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex V of Council Directive 93/42/EEC as amended by 2007/47/EC.

Place of Issue: Refer to Manufacturer's Address above

Signature: Susan Lin Date: Feb. 28, 2019

Title/Position: Susan Lin, Associate Director, Regulatory Affairs

Signature: Adnyl Grovas Date: 27 FEB 2019

Title/Position: Adnyl Grovas, Director, Quality Assurance Director

## ATTACHMENT 1

Manufacturer's Name: ETHICON, LLC  
Product: DERMABOND™ Topical Skin Adhesive  
MDD TF Number: 100142393

Product Code List	Product Description
AHV6	High Viscosity DERMABOND™ Topical Skin Adhesive
AHV12	High Viscosity DERMABOND™ Topical Skin Adhesive
AHVM12	High Viscosity DERMABOND™ Mini Topical Skin Adhesive
APP6	High Viscosity DERMABOND™ ProPen Topical Skin Adhesive
APPXL6	High Viscosity DERMABOND™ ProPenXL Topical Skin Adhesive
ANX6	DERMABOND ADVANCED™ Topical Skin Adhesive
ANX12	DERMABOND ADVANCED™ Topical Skin Adhesive