100154656 | Rev: 11

Johnson Johnson International

LEONARDO DA VINCILAAN 15 BE-1831 DIEGEM – Belgium

DECLARATION OF CONFORMITY

Manufacturer's Name: Johnson & Johnson International

Manufacturer's Address: c/o European Logistics Centre

Leonardo Da Vincilaan, 15

BE-1831 Diegem,

Belgium

Product: PROCEED™ Ventral Patch

Product Codes and Description: See Attachment 1

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 44756

MDD DD Number: ADAPTIV No. 100142385

EC Class III Device Declaration

We, Johnson & Johnson International, 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 Design Examination Certificate No. CE 543381, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC.

EC Quality System Certificate No. CE 589698, issued by the BSI Group The Netherlands B.V. Notified Body Number 2797, in accordance with Annex II Section 3.2 of Council Directive 93/42/EEC as amended by 2007/47/EC.

Place of Issue: Refer to Manufacturer's Address above

Signature: Val Ruth Beyer

Date: March 30, 2020

Title/Position: Valerie Smith Beyer, Associate Director, Regulatory Affairs

Signature: Date: MARCH 31, 2020

Title/Position: Veronica Ysunza, Quality Assurance Manager

Regulatory Affairs Submission Declaration of Conformity DoC for PROCEED Ventral Patch

100154656 | Rev: 11

ATTACHMENT 1

Manufacturer's Name:

Johnson & Johnson International

Product:

PROCEED™ Ventral Patch

MDD DD Number:

ADAPTIV No. 100142385

List of Product Codes:

Product Code	Product Description	Product Dimensions	Packaging Description
PVPS	PROCEED Ventral Patch - Small	4.3cm x 4.3cm	1 device per pouch, 2 pouches per package
PVPM	PROCEED Ventral Patch - Medium	6.4cm x 6.4cm	1 device per pouch, 2 pouches per package