

Johnson & Johnson International

LEONARDO DA VINCI LAAN, 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: PDS™ II (Polydioxanone) Monofilament Suture, Dyed and Undyed

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

Classification: Class III (Annex IX, Rule 8)

GMDN Code: 16584

MDD DD Number: 100142376

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 00414, 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:



Date:

July 1, 2020

Title/Position:

Elliott Jang, Associate Director, Regulatory Affairs

Signature:



Date:

JULY 01, 2020

Title/Position:

Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: PDS™ II (Polydioxanone) Monofilament Suture, Dyed and Undyed
MDD DD Number: 100142376

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.5 – 5.0 (Metric)
Suture Length	7, 10 cm (with Absolok), 20 cm - 240 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	No
Triclosan Maximum Levels (µg/m)	N/A
Accessories to suture type	Absolok Clips, Ethi-Endo-Suture Set
Needled/Non-Needled	Needled / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	6 mm - 110 mm
Needle Wire Diameter	0.15 mm – 1.44 mm

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100163694 | Rev: 14
DoC for PDS™ II Suture – Non-significant changes approved after the 26th May 2021 as
per Transitional Provisions of MDR Article 120.3

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The transitional provisions specified in MDR Article 120(3) prohibit manufacturers from issuing new Declaration of Conformities or amending, modifying, supplementing any existing MDD Declaration of Conformity from 26th May 2021.

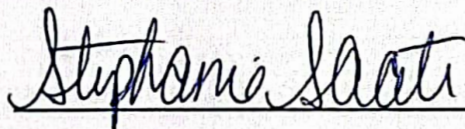
This letter is to confirm that Ethicon Wound Closure and Healing has reviewed and approved the change(s) detailed in the table below. These changes do not represent a change in design or intended purpose under MDR Article 120(3). Declaration of Conformity 100163694 | Rev: 14 DoC for PDS™ II Suture remains valid.

Changes Approved:

Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
30-JUN- 2022	101014129 100909440	CE 00414	3477740	Update per template FM-0001846 – no impact to DoC Updated Section A.4 to document BSI approval for the addition of the Janssen Pharmaceutical, Athens GA site as a raw material supplier of P-Dioxanone monomer used in the manufacture of PDS II Suture by Johnson & Johnson International.
14-Jun- 2022	100953227	CE 555601	3513637	Review of DoC initiated as DEC is renewed –no impact to DoC

Place of Issue: Refer to Manufacturer's Address above

Signature:
(wet sign only)

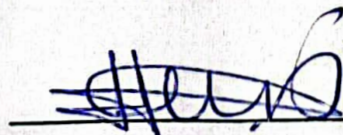


Date: 21-Dec-2022

Title/Position:

Stephanie Saati, Associate Director, Regulatory Affairs

Signature:
(wet sign only)



Date: 11-JAN-2023

Title/Position:

Veronica Ysunza, Quality Assurance Manager