

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™ Plus Antibacterial (polydioxanone) Suture

Product Range: See Attachment 1 for Product Range

Classification: Class III (Annex IX, Rule 8 and Rule 13)

GMDN Code: 47362

MDD DD Number: 100193159

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 536533, 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: Debbie Fazen Date: 5/21/2021

Title/Position: Debbie Fazen, Associate Director, Regulatory Affairs

Signature: [Signature] Date: 5/25/2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International
Product: PDS™ Plus Antibacterial (polydioxanone) Suture
MDD DD Number: 100193159

Suture Characteristic	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	35 cm - 245 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet
Suture Coated/Uncoated	Uncoated
Multifilament / Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels	≤ 2360 µg/m
Accessories to suture type	N/A
Suture 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 Colour	Silver / Black
Needle Length	7.9 mm - 70 mm
Needle Wire Diameter	0.20 mm – 1.55 mm

SUPPLEMENTARY INFORMATION

Supplementary Information to MDD Declaration of Conformity

Supplementary Information to MDD Declaration of Conformity 100227068 | Rev: 20
DoC for PDS Plus Antibacterial 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 100227068 | Rev: 20 DoC for PDS Plus Antibacterial Suture remains valid.

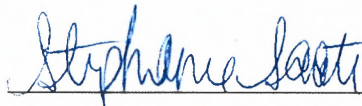
Changes Approved:

Date	ADAPTIV Reference Number	Certificate Numbers (if applicable for the change)	NB Reference Number (if applicable for the change)	Changes Approved
See Signature	101030398	CE 536533	3297412	Shelf-life increase from 2 years to 4.5 years for PDS plus Antibacterial (polydioxanone) Suture
			3562181	Triclosan Shelf life Extension from 5 years to 7 years
			3477751	Addition of the Janssen Pharmaceutical Athens GA site as a

				raw material supplier of P-Dioxanone monomer used in the manufacture of PDS Plus Antibacterial (polydioxanone) Suture by Johnson & Johnson International. Adding header to the DoC
15-Jun-2022	100953227	CE 536533	3513637	Review of DoC initiated as DEC is renewed –no impact to DoC Conversion of the SS2 Line at Ethicon, Inc., San Angelo, TX for EO Sterilization of absorbable products utilizing the X Cycle.

Place of Issue: Refer to Manufacturer's Address above

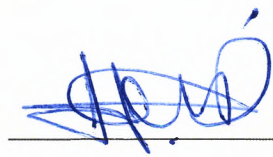
Signature:
(wet sign only)



Date: 02-Feb-2023

Title/Position: Stephanie Saati, Associate Director, Regulatory Affairs

Signature:
(wet sign only)



Date: 07-Feb-2023

Title/Position: Veronica Ysunza, Quality Assurance Manager