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:	**ULTRAPRO™ Hernia System**
Product Codes and Description:	See Attachment 1
Classification:	Class III (Annex IX, Rule 8)
GMDN Code:	44756 (Composite-Polymer Surgical Mesh)
MDD DD Number:	100159483

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 505757, 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: Somerville, New Jersey, USA,

Signature: _____ Date: May 21, 2021

Title/Position: Susan Lin, Associate Director, RA

Place of Issue: Diegem, Belgium ,

Signature: _____ Date: MAY 21, 2021

Title/Position: Veronica Ysunza, Quality Assurance Manager

ATTACHMENT 1

Manufacturer's Name: Johnson & Johnson International

Product: **ULTRAPRO™ Hernia System**

MDD DD Number: 100159483

Product Code	Product Description	Size		Packaging
		ONLAY	UNDERLAY	
UHSM1	ULTRAPRO Hernia System Medium	6cm x 12cm	7.5cm	1 Piece Per Box
UHSM	ULTRAPRO Hernia System Medium	6cm x 12cm	7.5cm	3 Pieces Per Box
UHSM6	ULTRAPRO Hernia System Medium	6cm x 12cm	7.5cm	6 Pieces Per Box
UHSL1	ULTRAPRO Hernia System Large	6cm x 12cm	10cm	1 Piece Per Box
UHSL	ULTRAPRO Hernia System Large	6cm x 12cm	10cm	3 Pieces Per Box
UHSL6	ULTRAPRO Hernia System Large	6cm x 12cm	10cm	6 Pieces Per Box
UHSOV1	ULTRAPRO Hernia System Oval	6cm x 12cm	10cm x 12cm	1 Piece Per Box
UHSOV	ULTRAPRO Hernia System Oval	6cm x 12cm	10cm x 12cm	3 Pieces Per Box

Form Non-PPE
Quality System
Franchise Restricted Substances Evaluation Form (Shared)

100575963 v1
CO: 100606125

Revision History for 100723004

Summary of Changes	
Revision Number	**Description of Change(s)**
1	New Document

This form supports 100576010 Franchise Restricted Substances Screening Procedure (Shared)

Section A – Technical File Information

DHF Number	100159483
DHF Title	*ULTRAPRO Hernia System*
Business Unit/Platform	*Ethicon Inc./ HERNIA MESH*
Responsible R&D Team Member	*Susan Cooper, Kai Thiemann*
Start Date	*April 28, 2019*

Product Details

Product Code	Product Description	Rationale for selecting the representative product	Is there a Patient Contact Pathway? Y/N**
N/A	**N/A**	**See Appendix All SKU's were screened, no representative product was required.**	**See Appendix for Patient Contact status of SKU**

**If the Patient Contact Pathway determination, as expressed below, is "N" for all devices covered then the form can be approved and further action is not required.
Per the MDR, Patient Contact Pathway is defined as:
"Devices, or those parts thereof or those materials used therein that:
— are invasive and come into direct contact with the human body,
— (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
— transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body"

Section B - Material Specification

Complete a table for each material used in the device.

Material Description	See APPENDIX for Details
RS-M-Spec	See APPENDIX for Details
Material Category	< plastics and rubber, metals, electronics, adhesives, packaging, colorants/coatings/oils, glass > See APPENDIX for Details
Material Type	<metals, mixtures, plastics> See APPENDIX for Details
Material Specification/ Industrial Standard or Reference	See APPENDIX for Details
Material Supplier Name	See APPENDIX for Details

RS-M-Spec Composition Details

CAS Number	Chemical Name	Structural Formula (If no CAS available)	Intentional Constituent or Residual Trace	Unit of Measure (ppm or %)	Nominal Value (Concentration Amount)	Lower Limit >= Value	Upper Limit <= Value
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Copy/paste tables from above for all materials

Section C - Restricted Substance Screening Results

CMR Determination	☒ Verified None Present ☐ Verified Presence but Below Threshold ☐ Verified Presence Above Threshold - FURTHER ACTION IS REQUIRED <Provide relevant additional information on CMRs>
EDC Determination	☒ Verified None Present ☐ Verified Presence but Below Threshold ☐ Verified Presence Above Threshold - FURTHER ACTION IS REQUIRED <Provide relevant additional information on EDCs>

Decision
☒ Further Action is NOT required as no CMRs were identified above the allowable threshold
☒ Further Action is NOT required as no EDCs were identified above the allowable threshold
☐ Further Action is required as one or more CMRs were identified above the allowable threshold. A justification and labeling is required (Sections C&D) for continued use of the substances
☐ Further Action is required as one or more EDCs were identified above the allowable threshold. A justification and labeling is required (Sections C&D) for continued use of the substances

Approval of evaluation

Approval may be completed by either signing and dating the form below, or by approval of the applicable individual in the local PLM system. In the case of utilizing the PLM system, enter “See PLM system” in the approval table below.

Product Steward Name (Print)	**Don Butler**
Product Steward Signature	**See ADAPTIV**
Date	**See ADAPTIV**

Section D – Justification for Continued Usage of RS Material

Analysis and estimation of potential patient or user exposure to the substance
Not Applicable
Analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives
Not Applicable
Rationale as to why possible substance and/or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials
Not Applicable
Where applicable and available, the latest relevant scientific committee guidelines in accordance with MDR guidelines on phthalates and other CMRs and EDCs
Not Applicable

Note: Please enter "N/A" for Not Applicable in any fields which are not required to be otherwise populated

Approvals

Approvals may be completed by either signing and dating the form below, or by approval of the applicable individuals in the local PLM system. In the case of utilizing the PLM system, enter “See PLM system” in the approval table below.

R&D Management Level Name (Print)	**Susan Cooper or Kai Thiemann**
R&D Management Level Signature	**See ADAPTIV**
Date	**See ADAPTIV**
Medical Affairs Management Level Name (Print)	**Niels-Derrek Schmitz**
Medical Affairs Management Level Signature	**See ADAPTIV**
Date	**See ADAPTIV**

APPENDIX A

TF# 100159483| Issued Date: 26 April 2019

Product Name	Product SKUs	Patient Contact per MDR (Y/N)	Material Specification / Reference / Standard	Material Supplier Name	RS-M-Spec ID	RS present > 0.1% in Raw Material Used (Y/N)	IF RS present		Restricted Substance name and CAS #	Further Action required due to RS presence
							CMR1a/b (Y/N)	EDC (Y/N)		
ULTRAPRO Hernia System Large	UHSL	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene monofilament fiber_JnJ Make)	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Large	UHSL1	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene monofilament fiber_JnJ Make)	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Large	UHSL6	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene monofilament fiber_JnJ Make)	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Medium	UHSM	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene monofilament fiber_JnJ Make)	NA	1391	N	N	N	NA	N

ULTRAPRO Hernia System Medium	UHSM1	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Medium	UHSM6	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Oval	UHSOV	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene	NA	1391	N	N	N	NA	N
ULTRAPRO Hernia System Oval	UHSOV1	Y	Finished Goods Specification Ultrapro Hernia System FPS-0010011 (Absorbable poliglecaprone-25 monofilament fiber and Nonabsorbable polypropylene	NA	1391	N	N	N	NA	N

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 505757**

Issued To: **Johnson & Johnson International**
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

In respect of:

ULTRAPRO™ Hernia System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-06-28** Date: **2021-03-05** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 505757

Issued To:

Johnson & Johnson International
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Product: ULTRAPRO™ Hernia System

Product Code	Description	Size		Packaging
		Onlay	Underlay	
UHSM1	ULTRAPRO Hernia System Medium	6 cm x 12 cm	7.5 cm	1 Piece per Box
UHSM	ULTRAPRO Hernia System Medium	6 cm x 12 cm	7.5 cm	3 Pieces per Box
UHSM6	ULTRAPRO Hernia System Medium	6 cm x 12 cm	7.5 cm	6 Pieces per Box
UHSL1	ULTRAPRO Hernia System Large	6 cm x 12 cm	10 cm	1 Piece per Box
UHSL	ULTRAPRO Hernia System Large	6 cm x 12 cm	10 cm	3 Pieces per Box
UHSL6	ULTRAPRO Hernia System Large	6 cm x 12 cm	10 cm	6 Pieces per Box
UHSOV1	ULTRAPRO Hernia System Oval	6 cm x 12 cm	10 cm x 12 cm	1 Piece per Box
UHSOV	ULTRAPRO Hernia System Oval	6 cm x 12 cm	10 cm x 12 cm	3 Pieces per Box

First Issued: **2006-06-28** Date: **2021-03-05** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 505757

Issued To:

Johnson & Johnson International
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Certificate History

Date	Reference Number	Action
28 June 2006	10072928	First issue.
22 June 2011	10123643	Certificate renewal, change to lacquer composition of foil packaging and the reformatting of product descriptions.
06 September 2012	10136503	Change of address. Administrative update to certificate format.
02 November 2012	10129846	Change of processing aid Tween 65 from synthetic to animal origin.
28 August 2015	10155544	Changes to labels and IFU.
18 March 2016	10159048	Change in DuPont™ Tyvek® flash-spinning technology (1073B Transition Tyvek®).
17 June 2016	10160536	Certificate renewal.
27 February 2019	8679791	Modifications to IFU: reformat of indications statement, addition of warnings, standardization of wording, and addition of MRI safety statement.
2 March 2019	8952310	Traceable to NB 0086.

First Issued: **2006-06-28** Date: **2021-03-05** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 505757

Issued To:

Johnson & Johnson International
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Certificate History

Date	Reference Number	Action
Current	3218669	Certificate Renewal. Manufacturing Change: Transfer in-house to Nordstedt, Germany site of prewinding, twisting and rewind processes for partly absorbable meshes.

First Issued: **2006-06-28** Date: **2021-03-05** Expiry Date: **2024-05-26**