
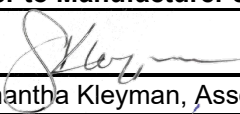




English			
 LEONARDO DA VINCILAAN 15 BE-1831 DIEGEM - Belgium			
<b>EU DECLARATION OF CONFORMITY</b>			
<b>Manufacturer's Name</b>	Johnson & Johnson International		
<b>Manufacturer's Address</b>	c/o European Logistics Centre Leonardo Da Vincilaan, 15 BE-1831 Diegem Belgium		
<b>Manufacturer's Single Registration Number (SRN)</b>	BE-MF-000008018		
<b>Notified Body Name</b>	BSI Group The Netherlands B.V		
<b>Notified Body Identification Number</b>	2797		
<b>Technical Documentation Number</b>	100696223		
<b>Product Name</b>	ULTRAPRO™ Mesh and ULTRAPRO ADVANCED™ Mesh		
<b>Product Code(s)/Product Range and Description</b>	Please refer to Attachment 1 Please refer to Attachment 2		
<b>Intended Purpose</b>	ULTRAPRO™ Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.		
	ULTRAPRO ADVANCED™ Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.		
<b>Classification</b>	Class III (Annex VIII, Rule 8)		
<b>GMDN Code</b>	44756 – Extra-gynaecological surgical mesh, composite-polymer		
<b>EMDN Code</b>	P900204 Surgical Meshes, More Than One Component		
<b>Basic UDI-DI</b>	<b>Basic UDI-DI Device Name</b>	<b>Basic UDI-DI Device Model</b>	<b>Basic UDI-DI</b>
	ULTRAPRO Mesh	ULTRAPRO	0705031a014524X
	ULTRAPRO ADVANCED Mesh	ULTRAPRO	0705031a014524X
<b>Common Specifications</b>	Common Specifications have not been issued		
<b>This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.</b>			
We, Johnson & Johnson International hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745. This declaration is made on the basis of: EU Technical Documentation Assessment Certificate Number MDR 730047, issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745. EU Quality System Certificate Number MDR 729796, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.			

SIGNATURE SECTION			
<b>Place of Issue</b>	<b>Refer to Manufacturer's Address above</b>		
<b>Signature</b>		<b>Date</b>	15-Sep-2023
<b>Name/Title</b>	Samantha Kleyman, Associate Director Regulatory Affairs		
<b>Signature</b>		<b>Date</b>	18- Sep-2023
<b>Name/Title</b>	Veronica Ysunza, Quality Assurance Manager		
	<b>Manufacturer's Person Responsible for Regulatory Compliance</b>		


**Note:** The English DoC is considered the "EN Master DoC". The dated signature present in the "EN Master DoC" will represent the date of validity for any translated DoCs.

**ATTACHMENT 1**

 LEONARDO DA VINCILAAN 15 BE-1831 DIEGEM - Belgium <b>EU DECLARATION OF CONFORMITY</b>	
<b>Manufacturer's Name</b>	Johnson & Johnson International
<b>Technical Documentation number</b>	100696223
<b>Product and Trade names(s)</b>	ULTRAPRO™ Mesh
<b>Intended Purpose</b>	ULTRAPRO™ Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.

Product Name	Product Code	Product Description
ULTRAPRO™ Mesh	UMF1	15X17CM
	UML1	30X30CM
	UMM1	15X15CM
	UMM3	15X15CM
	UMN1	10X15CM
	UMN3	10X15CM
	UMP3	10X12CM
	UMR3	7.6X15CM
	UMS1	6X11CM
	UMS3	6X11CM
	UMT1	15X30CM

**ATTACHMENT 2**

 LEONARDO DA VINCILAAN 15 BE-1831 DIEGEM - Belgium <b>EU DECLARATION OF CONFORMITY</b>	
<b>Manufacturer's Name</b>	Johnson & Johnson International
<b>Technical Documentation number</b>	100696223
<b>Product and Trade names(s)</b>	ULTRAPRO ADVANCED™ Mesh
<b>Intended Purpose</b>	ULTRAPRO ADVANCED™ Mesh is indicated for the repair of abdominal wall hernias that require the addition of a reinforcing material to obtain the desired surgical result.

Product Name	Product Code	Product Description
ULTRAPRO ADVANCED™ Mesh	UPA612	6x12CM
	UPA37615	7.6x15CM
	UPA1015	10X15CM
	UPA1515	15X15CM
	UPA1530	15X30CM
	UPA3030	30X30CM
	UPA31015	10X15CM
	UPA31515	15X15CM
	UPA3612	6X12CM