





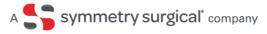
EU Declaration of Conformity

This EU Declaration of Conformity is issued under the sole responsibility of the O.R. Company Pty Ltd for the devices in Table 1 below that conforms with Annex IX Medical Device Regulation 2017/745.

Table 1

Table 1	_		
Manufacturer's Name:	The O. R. Company Pty Ltd		
Business Address:	4/47 Wangara Road, Cheltenham Victoria, Australia		
Manufacturer's Single Registration Number:	AU-MF-000010179		
Devices and Device Codes:	ManipulatOR™	UM-TV	
	Calmatanaia OD Tuba Sustana IM	CTS35-TV	
	ColpotomizOR Tube System™	CTS45-TV	
		UE-TVPRO-32	
	Uterine ElevatOR Pro™	UE-TVPRO-35	
		UE-TVPRO-37	
		UE-TVPRO-40	
		UE-LHPRO-32	
	Uterine ElevatOR Pro with Long	UE-LHPRO-35	
	Handle™	UE-LHPRO-37	
		UE-LHPRO-40	
		UE-OBPRO-32	
	Uterine ElevatOR Pro with	UE-OBPRO-35	
	OccludOR Balloon [™]	UE-OBPRO-37	
		UE-OBPRO-40	
	Uterine PositionOR™	UE-POR	
	Uterine PositionOR Pro™	UE-PLH	
	DUMI ManipulatOR™	DUMI-350A	
Basic UDI-DI:	93499670UTNMANPLTR58051BT		
Device Nomenclature Code as per EMDN:	U0899		
Classification:	Class IIa, Non-Implantable		
Classification rule as per Annex VIII:	Rule 7 - (all the above-mentioned devices except for DUMI-350A) Rule 5 - (only DUMI-350A)		
Notified Body:	BSI Group, The Netherlands B.V.		
Notified Body Number:	2797		
Conformity Assessment Procedure:	Conformity assessment as specified in Chapters I and III of Annex IX of Medical Device Regulation 2017/745 and including an assessment of the		
	technical documentation as specified in Section 4 of that Annex of at least		
	one representative device for each category of devices.		
MDR 2017/745 Certificate	MDR 755419		
Number:	WIDK 755419		
Intended Purpose of the Device:			
ManipulatOR [™]	Manipulation of the Uterus and ce	Manipulation of the Uterus and cervix in surgical procedures	
ColpotomizOR Tube System™	Manipulation of the uterus in laparoscopic gynecological procedures requiring maintenance of pneumoperitoneum. It is intended for insertion under direct visualization for secondary port location. The ColpotomizOR Tube System™ can be inserted trans-vaginally to establish a path of entry for minimally invasive instruments and can be used as a template for dissection for gynecologic surgical procedures. This instrument is a conduit		
	for the extraction of specimens.		







Uterine ElevatOR Pro [™] Uterine ElevatOR Pro with Long Handle [™] Uterine ElevatOR Pro with OccludOR Balloon [™] Uterine PositionOR [™]	Manipulation of the uterus, and injection of fluids or gasses during laparoscopic procedures. The device maintains pneumoperitoneum during laparoscopic procedures by sealing the vagina once colpotomy is performed.
Uterine PositionOR PRO™	Manipulation of the uterus, and injection of fluids during laparoscopic procedures
DUMI-350A	Manipulation of the uterus and injection of fluids during diagnostic laparoscopy, mini laparotomy, fertility exams, and salpingoplastic procedures.

The O. R. Company Pty Ltd shall establish, document and implement a Quality Management System and maintain its effectiveness throughout the lifecycle of the devices in Table 1 of this Declaration of Conformity according to Annex IX of Medical Device Regulation 2017/745. The Quality Management System certification, ISO 13485:2016 & EN ISO 13485:2016 Certificate Number: MD 649506, is issued by BSI Assurance UK Limited located at 389 Chiswick High Road, London W4 4AL, UK. The O. R. Company Pty Ltd shall inform BSI Group, The Netherlands B.V., (Notified Body Number: 2797) of any plan for substantial changes to the Quality Management System or the devices in Table 1 of this Declaration of Conformity according to Annex IX of Medical Device Regulation 2017/745.

The O.R. Company Pty Ltd shall comply with the requirements for technical documentation of the devices in Table 1 of this Declaration of Conformity according to Annex II and Annex III of Medical Device Regulation 2017/745.

The O.R. Company Pty Ltd shall review and document experience gained in the post-production phase of the devices in Table 1 of this Declaration of Conformity, including from Post-Market Clinical Follow-Up as referred to in Part B of Annex XIV, and to implement any necessary corrective action.

Name: Nicole Conway

Position: Quality Assurance & Regulatory Affairs Manager

Place of issuance: The O.R. Company Pty Ltd

Date: 27 June 2022

European Authorized Representative: Single Registration Number: BE-AR-000000106

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