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

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
	ColpotomizOR Tube System™	CTS35-TV CTS45-TV
	Uterine ElevatOR Pro™	UE-TVPRO-32 UE-TVPRO-35 UE-TVPRO-37 UE-TVPRO-40
	Uterine ElevatOR Pro with Long Handle™	UE-LHPRO-32 UE-LHPRO-35 UE-LHPRO-37 UE-LHPRO-40
	Uterine ElevatOR Pro with OccludOR Balloon™	UE-OBPRO-32 UE-OBPRO-35 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 Number:	MDR 755419	
Intended Purpose of the Device:		
ManipulatOR™	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™	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™ 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
	Registered Address:	Obelis S.A. Bd. Général Wahis 53 1030 Brussels, Belgium
	Phone:	+32.2.732.59.54
	Fax:	+32.2.732.60.03
	E-mail:	mail@obelis.net
	Representative:	Mr. Gideon ELKAYAM (CEO)