



DEVICE DETAILS

NAME OF DEVICE	MEDGYN FLEXIBLE CANNULA/KARMAN
ESTABLISHMENT NAME	BEN WAY ENTERPRISES SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB3356024-158195
BRAND NAME	MEDGYN
MEDICAL DEVICE CATEGORY	MD 0106 - Non-active instrument
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>MedGyn Curette is a sterile, disposable tubular cannula for the extraction of the contents of the uterus to be used in conjunction with a vacuum source. The curette comes in sizes ranging from 6 mm to 16 mm in diameter. For selection purposes, a general rule of the size in millimeters is equal to the number of weeks of gestation is used. Size 4 mm and 5 mm are additionally available in Flexible Curettes. All the devices are sterilized by ethylene oxide and do not include any medicinal substances. The devices do not contain latex. These devices have already been CE marked and have been in use on the European continent for nearly two decades. In that time there have been no product-related complaints or reports for any of these devices. There have been no new technological changes to these devices over this time period. The devices are expected to be used by professionals trained in Obstetrics and Gynecology. The devices made up of various plastic polymers including Cellulose Acetate, LDPE, HDPE, Styrene-Butadiene Copolymers and Acrylonitrile Butadiene Styrene Copolymer.</p>
DEVICE INTENDED PURPOSE	For curettage and evacuation of the endometrial contents during induced termination of pregnancy or after miscarriage or as a curative measure in cases of dysmenorrhea.
VALIDITY DATE OF REGISTRATION	05/01/2024 - 04/01/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	4mm Flexible	022004
2	5mm Flexible	022005
3	6mm Flexible	022006
4	7mm Flexible	022007
5	8mm Flexible	022008
6	9mm Flexible	022009

NO	NAME OF DEVICE	IDENTIFIER
7	10mm Flexible	022010
8	11mm Flexible	022011
9	12mm Flexible	022012

