



## DEVICE DETAILS

|                                      |  |
|--------------------------------------|--|
| <b>NAME OF DEVICE</b>                | MEDGYN FLEXIBLE CANNULA/KARMAN   |
| <b>ESTABLISHMENT NAME</b>            | BEN WAY ENTERPRISES SDN BHD  |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE  |
| <b>REGISTRATION NO</b>               | GB3356024-158195   |
| <b>BRAND NAME</b>                    | MEDGYN   |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 0106 - Non-active instrument  |
| <b>DEVICE GROUPING TYPE</b>          | FAMILY   |
| <b>DEVICE DESCRIPTION</b>            | <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> |
| <b>DEVICE INTENDED PURPOSE</b>       | 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.   |
| <b>VALIDITY DATE OF REGISTRATION</b> | 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     |

| <b>NO</b> | <b>NAME OF DEVICE</b> | <b>IDENTIFIER</b> |
|-----------|-----------------------|-------------------|
| 7         | 10mm Flexible         | 022010            |
| 8         | 11mm Flexible         | 022011            |
| 9         | 12mm Flexible         | 022012            |

