



## DEVICE DETAILS

|                                      |   |
|--------------------------------------|---|
| <b>NAME OF DEVICE</b>                | FLEXIBLE KARMAN CANNULA   |
| <b>ESTABLISHMENT NAME</b>            | BEN WAY ENTERPRISES SDN BHD   |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GA3490724-162960  |
| <b>BRAND NAME</b>                    | WOMANCARE GLOBAL  |
| <b>MEDICAL DEVICE CATEGORY</b>       | SINGLE-USE DEVICES  |
| <b>DEVICE GROUPING TYPE</b>          | FAMILY  |
| <b>DEVICE DESCRIPTION</b>            | Sizes 4-6mm directly compatible with the Ipas Single Valve Aspirator. All Flexible Karmen cannulae require adapters for use with Ipas MVA Plus® or Ipas Double Valve Aspirator. Disposable and packed sterile Softer, more flexible cannula may be better option for retroverted or retroflexed uterine position. All cannulas have either lines or dots space at intervals to assist in gauging depth of insertion/retraction. The Flexible Karman cannulae have series of dots - the first at 6cm from the tip and others at 1cm intervals. |
| <b>DEVICE INTENDED PURPOSE</b>       | Flexible Karman Cannula are intended for uterine aspiration/uterine evacuation in obstetrics and gynecologic patients.  |
| <b>VALIDITY DATE OF REGISTRATION</b> | 20/02/2024 - 19/02/2029   |

## LIST OF DEVICE

| NO | NAME OF DEVICE                     | IDENTIFIER |
|----|------------------------------------|------------|
| 1  | Flexible Karman Cannula, size 4mm  | FC4        |
| 2  | Flexible Karman Cannula, size 5mm  | FC5        |
| 3  | Flexible Karman Cannula, size 6mm  | FC6        |
| 4  | Flexible Karman Cannula, size 7mm  | FC7        |
| 5  | Flexible Karman Cannula, size 8mm  | FC8        |
| 6  | Flexible Karman Cannula, size 9mm  | FC9        |
| 7  | Flexible Karman Cannula, size 10mm | FC10       |
| 8  | Flexible Karman Cannula, size 12mm | FC12       |