

DEVICE DETAILS		
NAME OF DEVICE	ROVAC KARMAN CURETTES	
ESTABLISHMENT NAME	PRIMAMEDIK SDN BHD	
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE	
REGISTRATION NO	GB9249623-114992	
BRAND NAME	ROVAC	
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES	
DEVICE GROUPING TYPE	FAMILY	
DEVICE DESCRIPTION	The Karman Curette is a suction tip combined with a scraping surgical instrument with a ring-shaped or fenestrated tip which can be either rigid or malleable, having a sharp or blunt tip. The Rovac curettage tubing is connected to either wall suction or a suction canister, and to a suction tip such as a Karman curette. Body fluids and tissues are removed during surgical applications when suction is applied.	
DEVICE INTENDED PURPOSE	DKC: The Disposable Karman Curette (DKC) is a suction tip combined with a scraping surgical instrument that has a ring shaped or fenestrated tip. The DKC is indicated to scrape or remove tissue during gynaecological procedures.	
VALIDITY DATE OF REGISTRATION	13/12/2022 - 12/12/2027	

LIST OF DEVICE				
NO	NAME OF DEVICE	IDENTIFIER		
1	Karman Curette	DKC3006		
2	Karman Curette	DKC3007		
3	Karman Curette	DKC3008		
4	Karman Curette	DKC3009		
5	Karman Curette	DKC3010		
6	Karman Curette	DKC3011		
7	Karman Curette	DKC3012		
8	Karman Curette	DKC3206		
9	Karman Curette	DKC3207		
10	Karman Curette	DKC3208		
11	Karman Curette	DKC3209		

NO	NAME OF DEVICE	IDENTIFIER
12	Karman Curette	DKC3210
13	Karman Curette	DKC3211
14	Karman Curette	DKC3212
15	Karman Curette	DKC3306
16	Karman Curette	DKC3307
17	Karman Curette	DKC3308
18	Karman Curette	DKC3309
19	Karman Curette	DKC3310
20	Karman Curette	DKC3311
21	Karman Curette	DKC3312

