DEVICE DETAILS

NAME OF DEVICE	RESTYLANE SKINBOOSTERS VITAL
ESTABLISHMENT NAME	GALDERMA MALAYSIA SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GD42843959918
BRAND NAME	RESTYLANE
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	RESTYLANE SKINBOOSTERS VITAL IS A STERILE, TRANSPARENT GEL OF STABILIZED HYALURONIC ACID OF NON-ANIMAL ORIGIN. IT IS SUPPLIED IN A GLASS SYRINGE. THE PRODUCT HAS A BUILT IN DOSE-GUIDE, SMART CLICK SYSTEM, WHICH WHEN ACTIVATED CREATES A CLICKING SOUND TO INDICATE EACH INJECTED DOSE. THE 1 ML SYRINGE GIVES APPROXIMATELY 100 DOSES. THE CONTENTS OF THE SYRINGE ARE STERILIZED USING MOIST HEAT. THE PRODUCT IS FOR SINGLE USE ONLY. DISPOSABLE 29G TW (THIN-WALLED) NEEDLES, STERILIZED USING ETHYLENE OXIDE, ARE PROVIDED. TO ENSURE TRACEABILITY THE PATIENT RECORD LABEL (PART OF SYRINGE LABEL) SHOULD BE ATTACHED TO PATIENT RECORDS.
DEVICE INTENDED PURPOSE	THIS PRODUCT IS INTENDED TO RESTORE SKIN HYDROBALANCE, IMPROVE SKIN STRUCTURE AND THE ELASTICITY OF THE SKIN. IT SHOULD BE INJECTED IN THE DERMAL LAYER OF THE SKIN, PREFERABLY IN THE DEEPER PART OF DERMIS. BEFORE THE FIRST TREATMENT SESSION, IT IS RECOMMENDED TO CONTACT YOUR LOCAL GALDERMA REPRESENTATIVE OR RESTYLANE DISTRIBUTOR FOR MORE INFORMATION ABOUT INJECTION TECHNIQUES AND TRAINING OPPORTUNITIES. THIS PRODUCT IS ONLY INTENDED TO BE ADMINISTERED BY AUTHORIZED PERSONNEL IN ACCORDANCE WITH LOCAL LEGISLATION.
VALIDITY DATE OF REGISTRATION	08/09/2023 - 07/09/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Restylane Skinboosters Vital	011633
2	Terumo Short K-pack II	N/A
3	BD Hypoint®	N/A
4	Syringe barrel	N/A
5	Tip cap	N/A

NO	NAME OF DEVICE	IDENTIFIER
6	Luer-lock adapter	N/A
7	Shell	N/A
8	Plunger	N/A
9	Finger grip	N/A
10	Plunger rod	N/A
11	Restylane Skinboosters Vital	10-70401, 10-70402