



## DEVICE DETAILS

NAME OF DEVICE	RESTYLANE SKINBOOSTERS VITAL LIDOCAINE
ESTABLISHMENT NAME	GALDERMA MALAYSIA SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GD24598448617
BRAND NAME	RESTYLANE
MEDICAL DEVICE CATEGORY	MD 0204 - Non-active soft tissue implants
DEVICE GROUPING TYPE	SET
DEVICE DESCRIPTION	RESTYLANE SKINBOOSTERS VITAL LIDOCAINE IS A STERILE, TRANSPARENT GEL OF STABILIZED HYALURONIC ACID OF NON-ANIMAL ORIGIN WITH THE ADDITION OF 0.3% LIDOCAINE HYDROCHLORIDE. 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. THE ADDITION OF LIDOCAINE PROVIDES INCREASED OVERALL TREATMENT COMFORT. 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	17/11/2022 - 16/11/2027

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Restylane®; Skinboosters VitalLidocaine	011634
2	Restylane®; Skinboosters VitalLidocaine	10-73601, 10-73602
3	Plunger	N/A
4	Terumo Short K-pack II	N/A

NO	NAME OF DEVICE	IDENTIFIER
5	BD Hypoint®;	N/A
6	Syringe barrel	N/A
7	Tip cap	N/A
8	Luer-lock adapter	N/A
9	Shell	N/A
10	Plunger	N/A
11	Finger grip	N/A
12	Plunger rod	N/A

