Medical Device Authority Malaysia

# Public Search

Malaysia Medical Device Register (MMDR)

## DEVICE DETAILS

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|---|---|
| **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 |

| NO | NAME OF DEVICE | IDENTIFIER |
|---|---|---|
| 3 | Plunger | N/A |
| 4 | Terumo Short K-pack II | N/A |
| 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 |