



DEVICE DETAILS

NAME OF DEVICE	CRESPINE GEL
ESTABLISHMENT NAME	NEXGEN MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GD3657323-143685
BRAND NAME	MD055
MEDICAL DEVICE CATEGORY	MD 0202 - Non-active orthopaedic implants
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	Crespine gel is a class iii medical device currently certified by CE Certiso (CE2409). It is a visco-supplement indicated for treatment of pain symptoms and joint function disorders as a result of osteoarthritis in the knee or hip. Crespine gel is a trade name of the design name "hylan gel" which describes the composition of the product, which consists of chemically cross-linked Hyaluronic acid. Cross-linked hyaluronic acid forms a viscoelastic gel when it is mixed with water. Crespine gel is indicated for pain and joint function disorders as a result of de-generative deficits as a single injection treatment course. After the injection hyaluronic acid forms a layer on the surface of the joint cartilage and improves the pain symptoms.
DEVICE INTENDED PURPOSE	Crespine gel is indicated for pain and joint function disorders as a result of degenerative deficits (osteoarthritis). After the injection hyaluronic acid forms a layer on the surface of the joint cartilage and improves pain symptoms. Treatment areas of crespine gel are osteoarthritis of the knee or hip joint.
VALIDITY DATE OF REGISTRATION	07/08/2023 - 06/08/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	CRESPINE GEL	MD055