



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	CRESPINE GEL
<b>ESTABLISHMENT NAME</b>	NEXGEN MEDICAL SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GD3657323-143685
<b>BRAND NAME</b>	MD055
<b>MEDICAL DEVICE CATEGORY</b>	MD 0202 - Non-active orthopaedic implants
<b>DEVICE GROUPING TYPE</b>	SINGLE
<b>DEVICE DESCRIPTION</b>	<p>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.</p>
<b>DEVICE INTENDED PURPOSE</b>	<p>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.</p>
<b>VALIDITY DATE OF REGISTRATION</b>	07/08/2023 - 06/08/2028

## LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	CRESPINE GEL	MD055