Medical Devices - Product Registration

1. Product Information	
1.1 Product Name	Japet W+
1.2 Product Number	MDPR260210T0001
1.3 Intended Use	JAPET.W+ is indicated for people suffering from chronic and acute low back pain and is designed for ambulatory distraction of the lumbar spine. It can also be used by healthy people performing tasks involving heavy strain on the lumbar spine
1.4 Risk Classification	Class B
1.5 Medical Specialty	Orthopaedics
1.6 Model Information	Refer to Annex A for Model Information
1.7 First Approved Date	10-Feb-2026
1.8 Last Amendment Date	–
1.9 Retention Due Date	09-Feb-2027

2. Product Owner Information	
2.1 Product Owner Name	Japet Medical Devices
2.2 Product Owner Address	147 avenue Pierre Mauroy, Loos, 59120, France , France

3. Registrant Information	
3.1 Registrant Name	V-SHIELD ASIA PTE. LTD.
3.2 Registrant Address	101, CECIL STREET, #20-11, TONG ENG BUILDING, Singapore 069533

4. Importer Information
-

5. Manufacturing Site Information		
5.1	**Manufacturing Site 1**	
5.1.1	Manufacturing Site Name	Japet Medical Devices

5.1.2	Manufacturing Site Address	147 avenue Pierre mauroy, Loos, 59120, France , France

6. Approval Conditions

6.1 Change Notification	
6.1.1	PLC013 - Any technical/ review/ administrative change, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this device listing shall require approval from the Authority prior to supply of these medical devices, unless otherwise specified by the Authority. Failure to notify such changes to medical devices may result in suspension or cancellation of this device listing in accordance to Section 37(1)(b)(ii) of the Health Products Act.
6.1.2	PLC014 - Any notification change, as defined in GN-21 Guidance on Change Notification, made to medical devices registered under this device listing shall be notified to the Authority prior to supply of these medical devices, unless otherwise specified by the Authority. Failure to notify such changes may result in suspension or cancellation of this device listing in accordance to Section 37(1)(b)(ii) of the Health Products Act.
6.2 Change of Registrant or Product Owner	
6.2.1	PLC007 - A change of the Product Owner or Registrant may result in the suspension or cancellation of the Device Listing on the SMDR if the change has not been approved by HSA.
6.3 Other Regulatory Requirements	
6.3.1	PLC023 - The product owner shall assist the Health Sciences Authority with any request for information on medical devices registered under this listing. The product owner shall provide post-market support and assistance to the registrant for medical devices registered under this listing.
6.3.2	PLC024 - This device listing is valid on the condition that the registrant remains authorised by the product owner in accordance to the letter of authorisation (LOA).
6.3.3	PLC034 - All medical devices in this listing shall be labelled with Unique Device Identifier (UDI) and the relevant UDI data elements and shall be updated on the Singapore Medical Device Register (SMDR) by the respective UDI compliance dates as set out on the Authority's website.

7. Approved Pre-specified Changes

-

Annex A

Name as per Device Label	Identifier	UDI-DI	DM-DI	Description
JAPET.W+	SAYYMM1XXX & SAYYMM2XXX	(0)3770027792024 & (0)3770027792031		The dimensions of the JAPET.W+ T1 are 90 cm x 30 cm x 10 cm, which is suitable for a person of size S to L . The dimensions of the JAPET.W+ T2 are 110 x 30 cm x 10 cm, which is suitable for a person of size L to XXL .