Enabling Reliance Through Data

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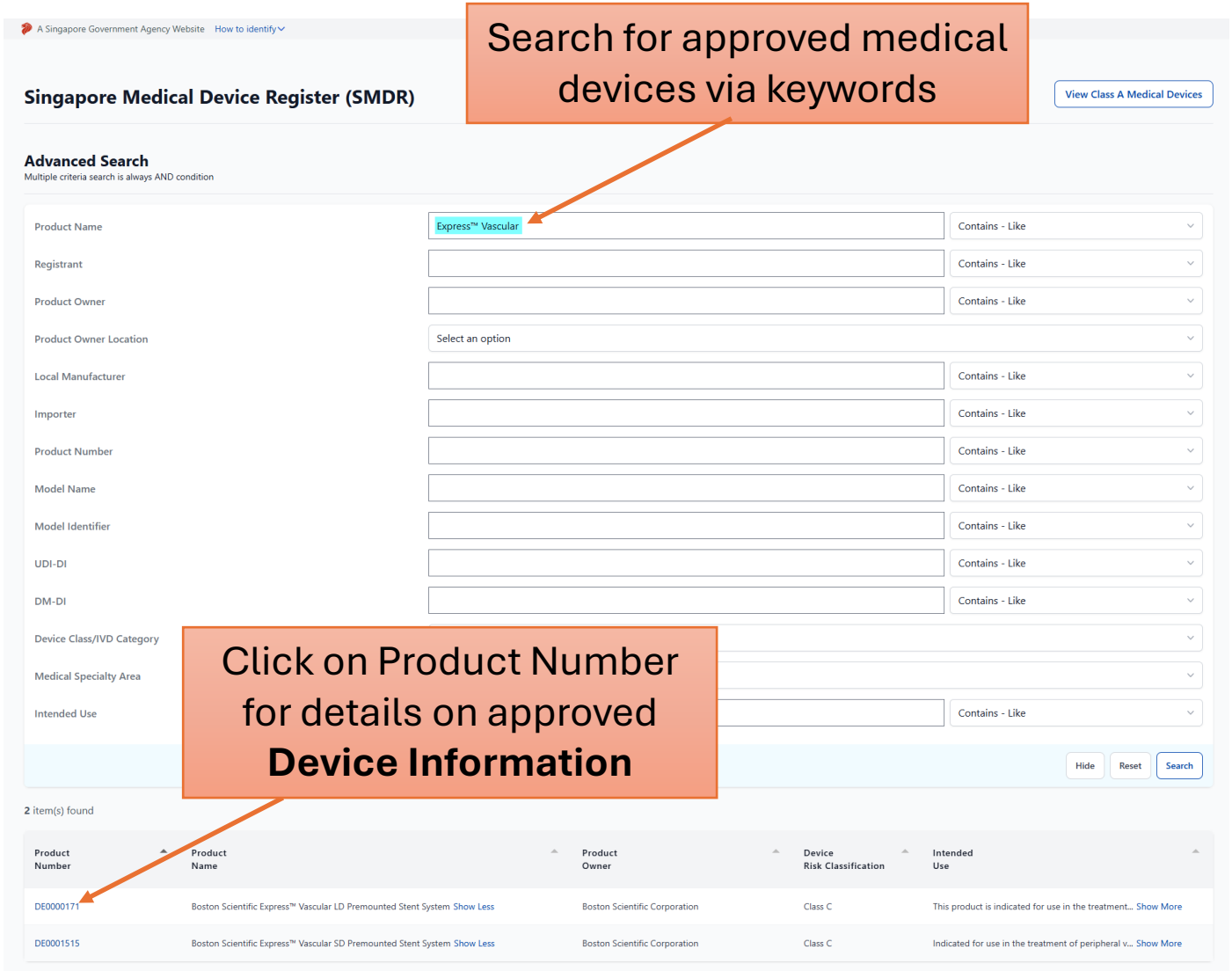
Singapore Medical Device Register (SMDR)

The Singapore Medical Device Register (SMDR) is the official HSA-published source of regulatory information on medical devices approved for supply in Singapore.

https://share.hsa.gov.sg/medics/PublicListing/Smdr/



How Regulators can use SMDR

Verification of Regulatory Status

1. Cross-check first registration date in Singapore
2. Cross-check update history (i.e. last Change Notification approval date)

Product Identification & Traceability

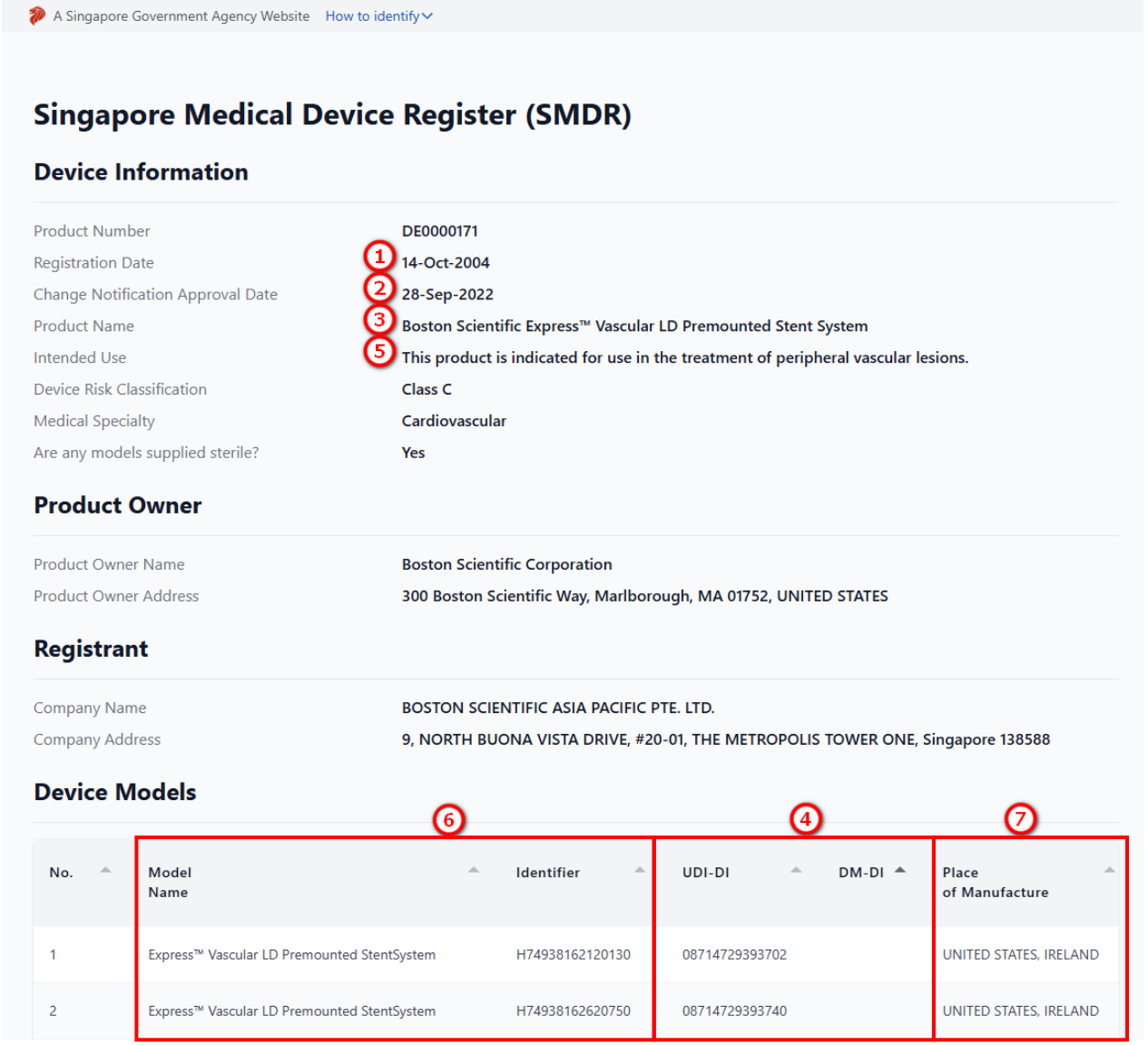
3. Verify device name (as per approved labelling)
4. Review UDI information (where available) for traceability

Validation of Device Claims

5. Compare marketed claims against intended use approved in Singapore

Supply Scope & Manufacturing Information

6. Identify approved device variants/models and model identifiers (as per approved labelling)
7. Review critical manufacturing site locations



A Singapore Government Agency Website How to identify

Singapore Medical Device Register (SMDR)

Device Information

Product Number	DE0000171
Registration Date	(1) 14-Oct-2004
Change Notification Approval Date	(2) 28-Sep-2022
Product Name	(3) Boston Scientific Express™ Vascular LD Premounted Stent System
Intended Use	(5) This product is indicated for use in the treatment of peripheral vascular lesions.
Device Risk Classification	Class C
Medical Specialty	Cardiovascular
Are any models supplied sterile?	Yes

Product Owner

Product Owner Name	Boston Scientific Corporation
Product Owner Address	300 Boston Scientific Way, Marlborough, MA 01752, UNITED STATES

Registrant

Company Name	BOSTON SCIENTIFIC ASIA PACIFIC PTE. LTD.
Company Address	9, NORTH BUONA VISTA DRIVE, #20-01, THE METROPOLIS TOWER ONE, Singapore 138588

Device Models

No.	(6) Model Name	(6) Identifier	(4) UDI-DI	(4) DM-DI	(7) Place of Manufacture
1	Express™ Vascular LD Premounted StentSystem	H74938162120130	08714729393702		UNITED STATES, IRELAND
2	Express™ Vascular LD Premounted StentSystem	H74938162620750	08714729393740		UNITED STATES, IRELAND