STEP FLEX

Made in Germany
by Step Flex GmbH, Marschallstraße 8, 79115 Freiburg

Distributed in Australia
by Impexis Pty Ltd ATF Step Flex Trust
ACN 096457215 ABN 28456617854
2/833 High St, Kew East VIC 3102
info@stepflex.com.au, Tel: 03 9842 6951
www.stepflex.com.au

Buying a medical device?

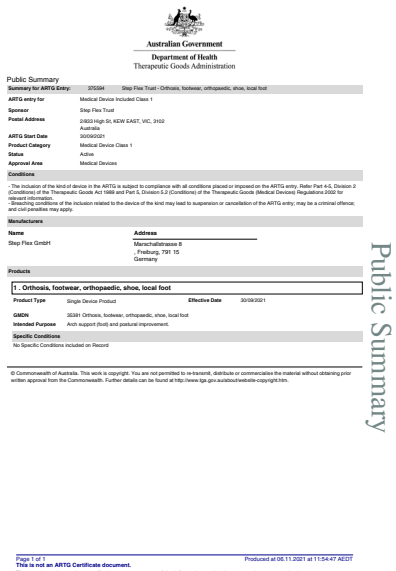
Check that it is registered with the TGA.
The publicly acccessible version of the Australian Register of Therapeutic Goods (ARTG) is the reference database of the Therapeutic Goods Administration (TGA). It provides information on the therapeutic goods that can be supplied in Australia.
If a therapeutic good is not entered on the ARTG, in nearly all cases it cannot be supplied in Australia.

Medical devices, including IVD medical devices, are regulated by the Therapeutic Goods Administration (TGA). We regulate medical devices in accordance with:

- The *Therapeutic Goods Act 1989* (the Act)
- The *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
- The *Therapeutic Goods Regulations 1990*

Any medical device (unless excluded or exempt under the Act) must be included in the ARTG before it can be legally imported into, supplied within or exported from Australia.

Source: https://www.tga.gov.au/publication/medical-device-inclusion-process (on 06/11/2021).



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375594	Step Flex Trust - Orthosis, footwear, orthopaedic, shoe, local foot
ARTG entry for	Medical Device Included Class 1	
Sponsor	Step Flex Trust	
Postal Address	2/833 High St, KEW EAST, VIC, 3102 Australia	
ARTG Start Date	30/09/2021	
Product Category	Medical Device Class 1	
Status	Active	
Approval Area	Medical Devices	

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Step Flex GmbH	Marschallstrasse 8 , Freiburg, 791 15 Germany

Products

1 . Orthosis, footwear, orthopaedic, shoe, local foot

Product Type	Single Device Product	Effective Date	30/09/2021
GMDN	35391 Orthosis, footwear, orthopaedic, shoe, local foot		
Intended Purpose	Arch support (foot) and postural improvement.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

Check for yourself!

Scan this QR Code to access the ARTG search page.
The Public Summary for Step Flex is shown in full overleaf.

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

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Sponsor	Step Flex Trust
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ARTG Start Date	30/09/2021
Product Category	Medical Device Class 1
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Approval Area	Medical Devices

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Manufacturers

Name	Address
Step Flex GmbH	Marschallstrasse 8 , Freiburg, 791 15 Germany

Products

1 . Orthosis, footwear, orthopaedic, shoe, local foot

Product Type	Single Device Product	**Effective Date**	30/09/2021
GMDN	35381 Orthosis, footwear, orthopaedic, shoe, local foot		
Intended Purpose	Arch support (foot) and postural improvement.		

Specific Conditions

No Specific Conditions included on Record

Public Summary