

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 <sup>□</sup> (the Act)
- The *Therapeutic Goods (Medical Devices) Regulations 2002* <sup>□</sup>/<sub>2</sub> (the Regulations)
- The Therapeutic Goods Regulations 1990 <sup>⊡</sup>

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).

# **Check for yourself!**

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



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#### 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, I Australia	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 Device	s		
Conditions				

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 (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 Effective Date 30/09/2021 Single Device Product GMDN 35381 Orthosis, footwear, orthopaedic, shoe, local foot Intended Purpose Arch support (foot) and postural improvement. **Specific Conditions** No Specific Conditions included on Record

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